ELITech Clinical Systems
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

ELITechGroup
EMPOWERING IVD

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs référencés dans la liste ci-jointe (2 pages), sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Ces dispositifs sont classés dans la catégorie « autre dispositif » puisqu'ils n'appartiennent ni à la liste A et liste B de l'annexe II et ni à la classe des autotests.

Cette déclaration est basée sur le contenu de chaque dossier technique et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2023).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents such as listed attached (2 pages) , conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.

These devices are classified in the "other device" category since they do not belong neither to list A or list B of annex II nor to self-testing class.

This declaration is based on the contents of each technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th , 2023).

Digitally signed
Date: 2023.06.0
Reason: MoldSi
Location: Moldo

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos referenciados en la lista adjunta (2 páginas), son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.

Estos dispositivos se clasifican en la categoría "otro dispositivo", ya que no pertenecen a la lista A ni a la lista B del anexo II, tampoco a la clase de autodiagnóstico.

Esta declaración se basa en el contenido de cada expediente técnico y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2023).

Sées, le 12 Mai 2021

Valérie LAMBERT,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00036

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Metabolites divers / Miscellaneous metabolites		
ALBUMIN	ALBU-0600/0700/0250/M830	53597
ALBUMIN ENVOY	ALBU-0850	
BILIRUBIN DIRECT 4+1	BIDI-0600/0250	53233
BILIRUBIN TOTAL 4+1	BITO-0600/0250	53229
BILIRUBIN TOTAL & DIRECT 4+1	BITD-0600	53229/53233
CREATININE ENVOY	CRSL-0850	53250
CREATININE JAFFE	CRCO-0600/0700	53251
CREATININE PAP	CRSL-M490	53250
CREATININE PAP SL	CRSL-0630/0250	
DIRECT BILIRUBIN	BIDI-M430	53233
DIRECT BILIRUBIN ENVOY	BIDV-0850	53233
GLUCOSE ENVOY	GPSL-0850	53301
GLUCOSE HK	GHSL-M490	
GLUCOSE HK SL	GHSL-0600/0250	
GLUCOSE PAP	GPSL-M690	
GLUCOSE PAP SL	GPSL-0507/0500/0707/0700/0250/0455/0497	
LACTATE	LACT-0100	53342
MICROPROTEIN PLUS	PRTU-0600/0250	53481
PHOSPHORUS	PHOS-0600/0230/M430	59123
PHOSPHORUS ENVOY	PHOS-0850	
TOTAL BILIRUBIN	BITO-M430	53229
TOTAL BILIRUBIN ENVOY	BITV-0850	53229
TOTAL PROTEIN	PROB-M830	53985
TOTAL PROTEIN ENVOY	PROB-0850	
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	
UREA	URSL-M830	53587
UREA ENVOY	URSL-0850	
UREA UV SL	URSL-0427/0420/0500/0507/0250/0455	
URIC ACID	AUML-M830	53583
URIC ACID ENVOY	AUVD-0850	
URIC ACID MONO SL	AUML-0497/0427/0420/0500/0507/0707/0250	
URIC ACID SL	AUSL-0250	
URINE PROTEIN	PRTU-M230	53481
Enzymes / Enzymes		
ALP (DEA) SL	PASL-0400/0420/0230	52928
ALP ENVOY	PIVD-0850	
ALP IFCC	ALPI-0230	
ALT ENVOY	ALSL-0850	52923
ALT/GPT	ALSL-M490	
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	
AMYLASE	AMSL-M430	52940
AMYLASE ENVOY	AMSL-0850	
AMYLASE SL	AMSL-0390/0400/0230	
AST/GOT	ASSL-M490	52954
AST ENVOY	ASVD-0850	
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	
CHOLINESTERASE	CHES-0053	52971
CK ENVOY	CKSL-0850	53003
CK-MB ENVOY	CMSL-0850	52994
CK-MB SL / CKMB	CMSL-0410/0430/0230	
CK NAC	CKSL-M230	53003
CK NAC SL	CKSL-0410/0430/0230	
GAMMA-GT	GISL-M230	53027
GAMMA-GT PLUS SL	GISL-0400/0420/0250	
GGT ENVOY	GISL-0850	
LDH ENVOY	LLSL-0850	53072
LDH IFCC	LLSL-M230	
LDH-L SL	LLSL-0400/0420/0230	
LIPASE	LPSL-0250	53108
LIPASE ENVOY	LPSL-0850	
LIPASE SL	LPSL-0230	
Electrolytes / Oligo-élements / Electrolytes / Trace-elements		
CALCIUM ARSENAZO	CALA-0600/0250/M430	45789
CALCIUM ENVOY	CALA-0850	
CHLORIDE	CHLO-0600/0250	60037
IRON ENVOY	FEFE-0850	54758
IRON FERENE	FEFE-0230/0600/M230	
MAGNESIUM ENVOY	MAGX-0850	46795
MAGNESIUM XB	MGXB-0250/0600/M430	
MAGNESIUM XYLIDYL	MAGX-0230/0600	
Lipides / Lipids		
CHOLESTEROL	CHSL-M690	53359
CHOLESTEROL ENVOY	CHSL-0850	
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	53391
CHOLESTEROL LDL SL 2G	LDLL-0230/0380/0390	53395
CHOLESTEROL SL	CHSL-0507/0500/0700/0707/0250/0455/0497	53359
HDL CHOLESTEROL	CHDL-0250/0600/M330	53391
HDL CHOLESTEROL ENVOY	HDLL-0850	
LDL CHOLESTEROL	CLDL-0250/M330	53395
LDL CHOLESTEROL ENVOY	LDLL-0850	
TRIGLYCERIDES	TGML-M690	53460
TRIGLYCERIDES ENVOY	TGML-0850	
TRIGLYCERIDES MONO SL NEW	TGML-0427/0425/0515/0700/0517/0707/0497	
TRIGLYCERIDES SL	TGML-0250/0455	

Vla

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Contrôles-Calibrants-Standards / Controls-Calibrators-Standards		
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	44696
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	41728
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	44698
CK-MB CONTROL	CKMB-0900	44693
ELICAL 2	CALI-0550	47868
ELITROL I	CONT-0060	47869
ELITROL II	CONT-0160	
GLUCOSE Standard 100 mg/dL	GLUP-0055	41818
HDL LDL CALIBRATOR	HLCA-0041	47868
ISE CONTROL I	ISCT-0046	47869
ISE CONTROL II	ISCT-0047	
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	53482
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	44702
UREA Standard 50 mg/dL	URUV-0055	53588
URIC ACID Standard 6 mg/dL	ACUR-0055	44704
Protéines spécifiques / Specific proteins		
ANTI-STREPTOLYSIN O	ASLO-0250	59055
CRP IP	ICRP-0400/M230	53705
CRP IP CALIBRATOR SET	ICRP-0043	41838
CRP IP CONTROL I	ICRP-0046	41839
CRP IP CONTROL II	ICRP-0047	
CRP WR	CRPW-0230	53705
CRP WR CALIBRATOR SET	CRPW-0043	41838
CRP WR CONTROL	CRPW-0045	41839
CRP WR ENVOY	CRPW-0850	53705
FERRITIN	IFRT-0230	53718
FERRITIN CALIBRATOR	IFRT-0042	41927
HAPTOGLOBIN IP	IHAP-0400	53737
HbA1c	HBAC-0240	59090
HbA1c CALIBRATOR SET	HBAC-0043	53315
HbA1c CONTROL L + H	HBAC-0049	44435
IgA IP	IIGA-0400	53760
IgG IP	IIGG-0400	53787
IgM IP	IIGM-0400	53795
µALBUMIN IP	IMAL-0400	53475
µALBUMIN IP CALIBRATOR SET	IMAL-0043	53477
µALBUMIN IP CONTROL I	IMAL-0046	53478
µALBUMIN IP CONTROL II	IMAL-0047	
OROSOMUCOID IP	IORO-0400	53606
PREALBUMIN IP	IPAL-0400	53957
PROTEIN IP CALIBRATOR SET	IPRO-0043	53593
RF CALIBRATOR	IRFA-0042	42230
RHEUMATOID FACTOR	IRFA-0230	55111
RHEUMATOLOGY CONTROL I	IRCT-0046	47869
RHEUMATOLOGY CONTROL II	IRCT-0047	
TRANSFERRIN IP	ITRF-0400	59041
Vitamines/Vitamins		
VITAMIN D	VITD-0250	54476
VITAMIN D CALIBRATOR SET	VITD-0043	54474
VITAMIN D CONTROL SET	VITD-0049	54475
ISE Solutions pour électrodes selectives d'ions / ISE Solutions for ion-selective electrodes		
ISE BASELINE SOLUTION ENVOY	ISBA-0850	59238
ISE CALIBRATORS	ISCA-0250	52867
ISE CALIBRATOR ENVOY	ISCV-0850	
ISE CLEANER/CONDITIONER	ISCC-0280	59058
ISE DILUENT	ISDI-0250	58237
ISE DILUENT ENVOY	ISDV-0850	
ISE REFERENCE SOLUTION	ISRS-0800	59238
ISE REFERENCE SOLUTION ENVOY	ISRS-0850	
Solutions de lavage pour les équipements ELITech Clinical Systems / Cleaning solutions for ELITech Clinical Systems Equipments		
ACID SOLUTION for ELITech Clinical Systems Analyzers	SLHC-5900	59058
SYSTEM CLEANING SOLUTION for ELITech Clinical Systems Analyzers	SLNA-5900	59058
SYSTEM SOLUTION	SLSY-5905	58236
SYSTEM SOLUTION for ELITech Clinical Systems Analyzers	SLSY-5900	
WASH SOLUTION A	SOLA-M163	59058
WASH SOLUTION B	WASH SOLUTION B	59058
Tests d'agglutination / Agglutination tests		
CRP LATEX	LXCR-0112	53707

Declaration of Conformity

HL-7-0229DC DOI 2015/08 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5392	Thrombin Time	55987

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 06 Aug 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
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Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7-DC-0814 Rev. 1

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5560	APTT Si L Minus	55981

I, the undersigned, declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: C.J. Sandercock Title: QA and Regulatory Affairs Officer

Signed: Date: 24 Nov 2020

Helena Biosciences Europe,
Gateshead, Tyne and Wear,
NE11 0SD, United Kingdom
Tel +44 (0)191 482 8440
info@helena-biosciences.com
www.helena-biosciences.com

EC REP
Prince Technologies B.V.
Waanderweg 62,
7812 HZ Emmen,
The Netherlands

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1038121-1

Manufacturer: MACHEREY-NAGEL GmbH & Co. KG
Valencienner Str. 11
52355 Düren
Germany

Products: Products for self-testing
- Single and multi-parameter disposable test strips for urine analysis
- Indicator test strips and papers for measurement of pH in urine

Replaces Certificate, Registration No.: HL 60119814 0001

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1038121-1

Manufacturer: MACHEREY-NAGEL GmbH & Co. KG
Valencienner Str. 11
52355 Düren
Germany

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design and development, manufacture and quality control
/02	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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MEDICA

Medica Corporation
5 Oak Park Drive
Bedford, Massachusetts 01730
Tel 781 275 4892
Fax 781 275 2731
www.medicacorp.com

Products For Health Care

Declaration of Conformity CE

Product Name:	Model/Type:
EasyLyte and accessories per attachment	EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li, Na/K/Ca/pH
EasyElectrolyte and accessories per attachment	EasyElectrolyte Na/K/Cl, Na/K/Li
EasyStat and accessories per attachment	pH/pCO2/pO2/Na/K/Ca/Hct, pH/pCO2/pO2/Na/K/Cl/Hct
EasyBloodGas and accessories per attachment	pH/pCO2/pO2

Manufacturer

Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA

Representative

EC REP Emergo Europe, Molenstraat 15
NL-2513 BH The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are in conformity with the Annex III, essential requirements and provisions of council Directive: 98/79/EC

Place and Date: Bedford, Massachusetts, USA, March 1, 2012

Signature:

Photios Makris

Name: Photios Makris

Title: Director of Regulatory Affairs

EasyBloodGas and EasyStat Accessories

Catalog No.	Accessory	EDMA Code
6201	EasyStat/EasyBloodGas pH Electrode	11 70 31 04
6202	EasyStat/EasyBloodGas pCO2 Electrode	11 70 31 04
6203	EasyStat/EasyBloodGas pO2 Electrode	11 70 31 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
6101	EasyBloodGas Reagent Module	11 70 31 10
6301	EasyBloodGas Troubleshooting Kit	21 04 10 01
6303	EasyQC Level 1 Blood Gas and Electrolyte Quality Control	11 70 31 50
6304	EasyQC Level 2 Blood Gas and Electrolyte Quality Control	11 70 31 50
6305	EasyQC Level 3 Blood Gas and Electrolyte Quality Control	11 70 31 50
2118	Daily Cleaning Solution Kit	11 01 01 27
6402	Red Test Dye Solution	11 70 31 90
6503	EasyBloodGas Capillary Tube Kit	21 04 10 01
6603	EasyBloodGas Demonstration Kit	21 04 10 01
6306	EasyBloodGas Sampler	21 04 10 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 04 10 01
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper (5 rolls)	21 04 10 01
6506	EasyBloodGas Sensor Module	21 04 10 01
6507	EasyStat/EasyBloodGas Valve Module	21 04 10 01
6508	Compression Plate	21 04 10 01
6518	Serial Cable, 25-pin	21 04 10 01
6537	Serial Cable, 9-pin	21 04 10 01
6520	Barcode Reader Kit	21 04 10 01
7101	EasyStat Reagent Module	11 70 31 10
7205	EasyStat/EasyElectrolyte Na Electrode	11 04 01 07
7206	EasyStat/EasyElectrolyte K Electrode	11 04 01 06
7207	EasyStat Ca Electrode	11 04 01 02
7208	EasyStat Cl Electrode	11 04 01 03
7301	EasyStat Troubleshooting Kit	21 04 10 01
7309	Bi-Level Hematocrit Quality Control	13 01 70 03
7603	EasyStat Demonstration Kit	21 04 10 01
7303	EasyStat/EasyBloodGas Capillary Tube Kit	21 04 10 01
7306	EasyStat Sampler	21 04 10 01
7304	EasyStat Pump Tube	21 04 10 01
7506	EasyStat Sensor Module	21 04 10 01
7302	Probe Wipers	21 04 10 01

EasyElectrolyte Accessories

Catalog No.	Accessory	EDMA Code
4102	EasyElectrolyte Reagent Module Na/K/Cl	11 03 01
4103	EasyElectrolyte Reagent Module Na/K/Li	11 03 01
7205	EasyStat/EasyElectrolyte Na Electrode	11 04 01 07
7206	EasyStat/EasyElectrolyte K Electrode	11 04 01 06
4203	EasyElectrolyte Cl Electrode	11 04 01 03
4204	EasyElectrolyte Li Electrode	11 04 01 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 04 10 01
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	Red Test Dye Solution	11 70 31 90
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Demonstration Kit, Na/K/Cl	21 04 10 01
4406	EasyElectrolyte Demonstration Kit, Na/K/Li	21 04 10 01
4404	EasyElectrolyte Capillary Tube Kit	21 04 10 01
4306	EasyElectrolyte Sampler	21 04 10 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 04 10 01
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper (5 rolls)	21 04 10 01
4506	EasyElectrolyte Sensor Module	21 04 10 01
4507	EasyElectrolyte Valve Module	21 04 10 01
4508	Compression Plate	21 04 10 01
7302	Probe Wipers	21 04 10 01
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 04 10 01
4539	EasyElectrolyte Sensor Module, Li	21 04 10 01
6518	Serial Cable, 25-pin	21 04 10 01
6537	Serial Cable, 9-pin	21 04 10 01
6520	Barcode Reader Kit	21 04 10 01

EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2070	EasyLyte EasySampler	21 04 10 01
2101	EasyLyte K+ Electrode	11 04 01 06
2102	EasyLyte Na+ Electrode	11 04 01 07
2113	EasyLyte Cl- Electrode	11 04 01 03
2106	EasyLyte Li+ Electrode	11 04 01 04
2150	EasyLyte Ca++ Electrode	11 04 01 02
2151	EasyLyte pH Electrode	11 70 31 02
2152	EasyLyte Disposable Reference Electrode	11 04 04 01
2103	EasyLyte Refrence Electrode	11 04 04 01
2258	EasyLyte Membrane Assembly	21 04 10 01
2120	EasyLyte Na/K 800mL Solutions Pack	11 03 01
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 03 01
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 03 01
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 03 01
2028	EasyLyte Na/K/Cl/Li 800mL Solutions Pack	11 03 01
2109	EasyLyte Na/K 400mL Solutions Pack	11 03 01
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 03 01
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 03 01
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 03 01
2026	EasyLyte Na/K/Cl/Li 400mL Solutions Pack	11 03 01
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
2843	EasyLyte Quality Control Sample Cups (60)	21 04 10 01
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 04 10 01
2108	EasyLyte Solutions Valve	21 04 10 01
2107	EasyLyte Sample Probe	21 04 10 01
2257	EasyLyte Sample Detector	21 04 10 01
2104	EasyLyte Tubing Kit	21 04 10 01
2100	EasyLyte Calcium Tubing Kit	21 04 10 01
2492	EasyLyte Internal Filling Solution (125mL)	11 04 04 90
2309	EasyLyte Wash Solution (50mL)	11 04 04 90
2111	EasyLyte Urine Diluent (500mL)	11 04 04 90
2577	EasyLyte Standard Solution, Urine (50mL)	11 04 04 90
2323	EasyLyte Probe Wipers (6)	21 04 10 01
2541	EasyLyte Printer Paper (3 rolls)	21 04 10 01

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 04 10 01
2596	EasyLyte Sample Cups 2.0mL (500)	21 04 10 01
10745	Anti-Evaporation Caps (500)	21 04 10 01
2293	EasyLyte Capillary Tubes	21 04 10 01
2590	EasyLyte Capillary Adaptor Kit	21 04 10 01
2292	EasyLyte Capillary Adaptor Cleaning Kit	11 04 04 90
2578	EasyLyte Red Dye Test Solution (50mL)	11 04 04 90
2572	EasyLyte Troubleshooting Kit	21 04 10 01
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 04 10 01
2105	EasyLyte Quarterly Operating Kit	21 04 10 01
2095	EasyLyte Maintenace Kit	21 04 10 01
2076	EasyLyte Sample Tray	21 04 10 01
2074	EasyLyte Sample Cup Retainer Ring	21 04 10 01
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 04 10 01

Abbott

Declaration of Conformity

Certificate Identification: DoC-3L79-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L79-22 3L79-32 3L79-42	45789	Calcium	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: 

Full Name: **Erik Muegge**

Position: **Mgr. Quality Operations Assurance**

Date of Approval: _26-FEB-2018_____

Signature: 

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: _26-FEB-2018_____

Date Issued: _26-FEB-2018_____

Place Issued: 65205 Wiesbaden, Germany

Supersedes: Not Appplicable

Effective (Date or Lot Number): _26-FEB-2018_____

Abbott

Declaration of Conformity

Certificate Identification: DoC-5P56-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
5P56-02	53356	Lipid Multiconstituent Calibrator	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Randox Laboratories Ltd, Ardmore, 55 Diamond Road, Crumlin, Co Antrim, BT29 4QY, UK.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: 

Full Name: **Erik Muegge**

Position: **Mgr. Quality Operations Assurance**

Date of Approval: 26-FEB-2018

Signature: 

Full Name: **Mark Littlefield**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 26-FEB-2018

Date Issued: 26-FEB-2018

Place Issued: 65205 Wiesbaden, Germany

Supersedes: Not Applicable

Effective (Date or Lot Number): 26-FEB-2018

Abbott

Declaration of Conformity

Certificate Identification: DoC-3L82-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH & Co. KG
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L82-22 3L82-42	53301	Glucose	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue, Charlottetown, Prince Edward Island C1E 2B9, Canada.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:
Full Name: **Erik Muegge**
Position: **Mgr. Quality Operations Assurance**
Date of Approval: 26-FEB-2018

Signature: 
Full Name: **Mark Littlefield**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 26-FEB-2018
Date Issued: 26-FEB-2018
Place Issued: 65205 Wiesbaden, Germany
Supersedes: Not Applicable
Effective (Date or Lot Number): 26-FEB-2018

SEKISUI DIAGNOSTICS
Because every result matters™

DECLARATION OF CONFORMITY

Manufacturer:	Sekisui Diagnostics P.E.I. Inc 70 Watts Avenue Charlottetown Prince Edward Island C1E 2B9 Canada
European Representative:	MDSS GmbH Schiffgraben 41 30175 Hannover Germany
Product:	Direct LDL Catalogue Number 1E31-20 GMDN Code: 53395
Classification:	General IVD
Conformity Assessment Route:	Annex III, self-certified

We hereby declare that the above-mentioned products meet the provisions of the Council Directive 98/79EC for in vitro diagnostic medical devices. All supporting documents are held by the manufacturer.

Place of Issue: Prince Edward Island, Canada

Signature: _____ 06-May-2019

Penny White
Senior Manager Regulatory Affairs
Sekisui Diagnostics PEI Inc.

Date

Sekisui Diagnostics P.E.I. Inc.
70 Watts Avenue
Charlottetown, Prince Edward Island
C1E 2B9 Canada
Tel: 902-566-1396 Fax: 902-628-6504
www.sekisuidiagnostics.com

SENTINEL
DIAGNOSTICS

EC DECLARATION OF CONFORMITY

For *in vitro* diagnostic medical devices (IVD) – Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy – Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry and immunochemistry, coagulation and rapid tests for immunology and serology" declares, under its own responsibility that the below listed devices comply with all essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (Legislative Decree nr. 322/2000).

It therefore declares and assures, under its own responsibility, that the devices:

1. comply with the applicable provisions of the Directive
2. are not included in the list A and B of Annex II of the Directive
3. are designed, manufactured and placed on the market according to the company certified quality system, in compliance with ISO 9001 and ISO 13485 as per indication expressed in Annex III of the Directive.

DICHIARAZIONE DI CONFORMITÀ CE

per dispositivi medico diagnostici *in vitro* IVD) – Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia – Via Robert Koch 2, fabbricante dei dispositivi appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che i dispositivi sotto elencati soddisfano i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che i dispositivi:

1. soddisfano le disposizioni applicabili della Direttiva
2. non sono inclusi nell'elenco A e B dell'Allegato III della Direttiva
3. sono progettati, fabbricati ed immessi in commercio nell'ambito dell'applicazione di un sistema di qualità aziendale dichiarato conforme e certificato secondo le norme ISO 9001 e ISO 13485 come descritto dall'Allegato III della Direttiva.

Code/Codice	Product Description/Nome prodotto
6K26-30	CRP Vario
6K26-41	CRP Vario
6K26-10	CRP Calibrator Set
6K26-12	CRP Calibrator WR
6K26-14	CRP Calibrator HS
6K26-21	CRP Control HS
6K89-30	Ammonia Ultra
6K91-30	Ceruloplasmin
4P79-30	UIBC Liquid
8L24-31	Creatinine (Enzymatic)
8L24-41	Creatinine (Enzymatic)
8L25-30	Lithium
6K89-20	Ammonia Controls
6K30-10	Clin Chem Cal
6K31-10	Plasmaproteins Cal 3x
1P93-30	Cystatin C
1P93-10	Cystatin C Calibrator

SENTINEL
DIAGNOSTICS

Code/Codice	Product Description/Nome prodotto
1P93-20	Cystatin C Control Set
6K25-10	CK-MB Calibrator
6K25-20	CK-MB Control
6K30-20	Clin Chem Control 1
6K30-21	Clin Chem Control 2
6K32-20	Immuno Control 1
6K32-21	Immuno Control 2
6K32-22	Immuno Control Set
6K90-20	Bile Acids Controls
6K98-10	Fructosamine Control 1
6K98-20	Fructosamine Control 2
4P80-30	Lambda Light Chains
6K24-30	Cholinesterase
6K25-30	CK-MB
6K22-30	Pancreatic Amylase
6K96-30	Kappa Light Chains
6K23-30	HBDH
6K90-30	Bile Acids
6K92-30	Dibucaine CHE
6K93-30	Copper
6K94-30	Fructosamine
6K95-30	Iron
6K95-41	Iron

Furthermore, the manufacturer declares to:

1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten (10) years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione delle Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo almeno di dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel Ch. SpA
A Legal Representative
Un Legale Rappresentante
Dr. Filippo De Luca

Date/Data
19/06/2015

Abbott

Declaration of Conformity

Certificate Identification: DOC-1E66-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1E66-05	41830	Bilirubin Calibrator	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Microgenics Corporation 46500 Kato Road Fremont, CA 94538 USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 23 Jun 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 15-Jun-2021
Date Issued: 23-Jun-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 23-Jun-2021

Abbott

Declaration of Conformity

Certificate Identification: DoC-7D74-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D74-22	53462	Triglyceride	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 22 Jul 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 11-Jul-2021
Date Issued: 22-Jul-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 22-Jul-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-7D55-SD-DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D55-22	52929	Alkaline Phosphatase	Self-declared
7D55-32	52929	Alkaline Phosphatase	Self-declared

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 16 Aug 2021

Signature: Tiffini Jenkins
Full Name: **TIffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 5-AUG-2021
Date Issued: 16-Aug-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 22-May-2017
Effective (Date or Lot Number): 16-Aug-2021

Abbott

Declaration of Conformity

Certificate Identification:	DoC-8G63-SD DELK TPM
Legal Manufacturer's Name:	Abbott GmbH
Legal Manufacturer's Address:	Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
8G63-22	53236	Direct Bilirubin	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue, Charlottetown, Prince Edward Island C1E 2B9, Canada.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker

Full Name: **Claudia Becker**

Position: **Director Quality Assurance**

Date of Approval: 22 Jul 2021

Signature: Tiffini Jenkins

Full Name: **Tiffini Jenkins**

Position: **Manager Regulatory Affairs**

Date of Approval: 11-Jul-2021

Date Issued: 22-Jul-2021

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 26-Feb-2018

Effective (Date or Lot Number): 22-Jul-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-3L81-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3L81-23 3L81-33 3L81-42	53251	Creatinine	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

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Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 22 Jul 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 11-Jul-2021
Date Issued: 22-Jul-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 22-Jul-2021

Abbott

Declaration of Conformity

Certificate Identification: DoC-2P56-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2P56-22 2P56-42	53072	Lactate Dehydrogenase	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

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Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 22 Jul 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 11-Jul-2021
Date Issued: 22-Jul-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 22-Jul-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-7D53-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D53-24	53599	Albumin BCG	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 22 Jul 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 11-Jul-2021
Date Issued: 22-Jul-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 22-Jul-2021

Abbott

Declaration of Conformity

Certificate Identification: DoC-7D75-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D75-22 7D75-32	53590	Urea Nitrogen	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 22 Jul 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 11-Jul-2021
Date Issued: 22-Jul-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 22-Jul-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-7D73-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D73-22	53989	Total Protein	Self-declared

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 22 Jul 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 11-JUL-2021
Date Issued: 22-Jul-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 22-Jul-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-7D81-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D81-22	52954	Aspartate Aminotransferase	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 10 Jun 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 9-JUN-2021
Date Issued: 10-Jun-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 10-Jun-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-7D63-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D63-22 7D63-42	53006	Creatine Kinase	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 10 Jun 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 9-JUN-2021
Date Issued: 10-Jun-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 10-Jun-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-7D58-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D58-22 7D58-42	52941	Amylase	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue, Charlottetown, Prince Edward Island C1E 2B9, Canada.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 10 Jun 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 9-Jun-2021
Date Issued: 10-Jun-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 10-Jun-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-1E65-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1E65-06	47868	Multiconstituent Calibrator	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Microgenics Corporation, 46500 Kato Road, Fremont, CA, 94538 USA .
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 10 Jun 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 9-Jun-2021
Date Issued: 10-Jun-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 16-May-2019
Effective (Date or Lot Number): 10-Jun-2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-7D56-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D56-22	52925	Alanine Aminotransferase	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue, Charlottetown, Prince Edward Island C1E 2B9, Canada.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 10 Jun 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 9-Jun-2021
Date Issued: 10-Jun-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 10-Jun-2021

TECHNOPATH
CLINICAL DIAGNOSTICS

DECLARATION OF CONFORMITY

Manufacturer
Techno-path Manufacturing Ltd.
Fort Henry Business Park,
Ballina,
Co. Tipperary,
Ireland

Product(s):

Product Name	Category	Catalogue Number
Multichem S Plus	Unassayed/single level	05P79-10
Multichem S Plus	Unassayed/single level	05P79-11
Multichem S Plus	Unassayed/single level	05P79-12
Multichem S Plus	Assayed/single level	05P78-10
Multichem S Plus	Assayed/single level	05P78-11
Multichem S Plus	Assayed/single level	05P78-12

GMDN:	47869
Conformity Route:	Annex III Self-Declared
Quality Management System:	EN ISO 13485:2016
QMS Certification No.:	Q51038520004 Rev 01
Issued By:	TÜV SÜD, Ridlerstraße 65, 80339 Munich, Germany
Expiry Date:	12 February 2025

Standards Applied: See attached list of standards for which documented evidence of compliance can be provided.

Techno-path Manufacturing Ltd. hereby declares that the product(s) specified above comply with the requirements listed in European Union In-vitro Diagnostic Medical Device Directive 98/79/EC.

I am fully responsible for all the information provided in this declaration. This declaration of conformity is valid from 18 **(Day)** FEB **(Month)** 2022 **(Year)**

TECHNOPATH
CLINICAL DIAGNOSTICS

Signed for and on behalf of Techno-path Manufacturing Ltd.,

B. Hass.

Bernd Hass,
SVP of Quality and Regulatory Affairs
Techno-path Manufacturing Ltd.

Ballina, Co.Tipperary 18-FEB-2022.
Place and Date of Issue

STANDARDS USED IN FULL OR PART FOR CE MARKING AS PER IVDD 98/79/EC

Standard	Title
EN ISO15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied.
EN ISO13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612:2002 + AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices – statistical aspects
ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
EN 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents

Abbott

Declaration of Conformity

Certificate Identification: DoC-3P39-SD DLK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3P39-22 3P39-42	53583	Uric Acid	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 19 May 2022

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 13-May-2022
Date Issued: 19 May 2022
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 19 May 2022

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0004FU
Basic UDI-DI Name: Detergent A
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
1J72-20	Detergent A	59058	W0201010185

Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 USA
Manufacturer SRN	US-MF-000017777
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue Charlottetown, Prince Edward Island CANADA C1E 2B9
Conformity Assessment Procedure	**Annex II and III**

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

Full Name:	Thomas Creel	Full Name:	Michele Smith-Waheed
Function:	Sr. Director, Instrument and Automation Quality	Function:	Associate Director, Regulatory Affairs
Signature:	Thomas Creel	Signature:	Michele Smith-Waheed
Date of Approval:	20-May-2022	Date of Approval:	20-May-2022
Signed for, and on behalf of:	Abbott Laboratories, 1915 Hurd Drive, Irving, TX 75038		
Date Issued:	20-May-2022	Place Issued:	Irving, Texas
Supersedes:	N/A	Effective (Date or Lot Number):	20-May-2022

EN	EU Declaration of Conformity	Basic UDI-DI	Basic UDI-DI Name
BG	ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ	Базов UDI-DI	Наименование на базов UDI-DI
CS	EU PROHLÁŠENÍ O SHODĚ	Základní UDI-DI	Název základního UDI-DI
DA	EU-OVERENSSTEMMELSESERKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄTSERKLÄRUNG	Basis-UDI-DI	Basis-UDI-DI Name
EL	ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ	Βασικό UDI-DI	Ονομασία βασικού UDI-DI
ES	DECLARACIÓN UE DE CONFORMIDAD	UDI-DI Básico	Nombre UDI-DI Básico
ET	ELi vastavusdeklaratsioon	Põhi-UDI-DI	Põhi-UDI-DI nimi
FR	Déclaration de conformité UE	IUD-ID de base	Nom IUD-ID de base
HR	EU IZJAVA O SUKLADNOSTI	Osnovni UDI-DI	Naziv osnovnog UDI-DI
HU	EU-MEGFELELŐSÉGI NYILATKOZAT	Alapvető UDI-DI	Alapvető UDI-DI neve
IT	Dichiarazione di conformità UE	UDI-DI di base	Nome UDI-DI di base
LV	ES atbilstības deklarācija	Pamata UDI-DI	Pamata UDI-DI nosaukums
LT	ES ATITIKTIES DEKLARACIJA	Bazinis UDI-DI	Bazinio UDI-DI pavadinimas
NO	EU-samsvarserklæring	Grunnleggende UDI-DI	Grunnleggende UDI-DI-navn
PL	DEKLARACJA ZGODNOŚCI UE	Kod Basic UDI-DI	Nazwa kodu Basic UDI-DI
PT	DECLARAÇÃO UE DE CONFORMIDADE	UDI-DI básico	Nome UDI-DI Básico
RO	Declarația de Conformitate UE	UDI-DI de bază	Nume UDI-DI de bază
SK	EÚ VYHLÁSENIE O ZHODE	Základný UDI-DI	Názov základného UDI-DI
SV	EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE	Grundläggande UDI-DI	Namn på grundläggande UDI-DI
TR	AB Uygunluk Beyanı	Temel UDI-DI	Temel UDI-DI İsmi

EN	Risk Class	List Number and Size Code	Product and Trade Name
BG	Клас според риска	Каталожен номер и код на размера	Име на продукта и търговско наименование
CS	Riziková třída	Katalogové číslo a koncové dvojčíslí určující velikost soupravy	Název produktu a obchodní název
DA	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og varemærkenavn
DE	Risikoklasse	Bestellnummer und Größencode	Produkt- und Handelsname
EL	Κατηγορία κινδύνου	Κωδικός Προϊόντος και Κωδικός Συσκευασίας	Προϊόν και Εμπορική Ονομασία
ES	Clase de riesgo	Número de referencia y código de tamaño	Producto y marca comercial
ET	Riskiklass	Katalooginumber ja suurusekood	Toote nimetus ja kaubanimi
FR	Classe de risque	Référence	Nom de produit et de marque
HR	Klasa rizika	Kataloški broj i oznaka pakiranja	Naziv proizvoda i zaštićeni naziv
HU	Kockázati osztály	Listaszám és készletkiszerelés-kód	Termék- és kereskedelmi név
IT	Classe di rischio	Numero di listino e codice formato	Prodotto e nome commerciale
LV	Riska klase	Kataloga numurs un izmēra kods	Produkta nosaukums un tirdzniecības nosaukums
LT	Rizikos klasė	Katalogo numeris ir dydžio kodas	Gaminio ir prekybinis pavadinimai
NO	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og handelsnavn
PL	Klasa ryzyka	Numer katalogowy	Nazwa produktu i nazwa handlowa
PT	Classe de risco	Número de lista e código de apresentação	Produto e nome comercial
RO	Clasă de risc	Număr de listă și cod dimensiune	Denumirea produsului și denumirea comercială
SK	Riziková trieda	Katalógové číslo	Názov produktu a obchodný názov
SV	Riskklass	Listnummer och storlekskod	Produkt och firmanamn
TR	Risk Sınıfı	Liste Numarası ve Boyut Kodu	Ürün ve Ticari İsmi

EN	GMDN Code	EMDN Code	Manufacturer (Name and Address)	Manufacturer SRN
BG	Код GMDN	Код EMDN	Производител (име и адрес)	ЕРН на производителя
CS	Kód GMDN	Kód EMDN	Výrobce (název a adresa)	Jediné registrační číslo výrobce
DA	GMDN-kode	EMDN-kode	Fabrikant (navn og adresse)	Fabrikants SRN
DE	GMDN-Code	EMDN-Code	Hersteller (Name und Adresse)	Hersteller-SRN
EL	Κωδικός GMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κωδικός EMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κατασκευαστής (Όνομα και Διεύθυνση)	SRN (Μοναδικός Αριθμός Μητρώου) Κατασκευαστή
ES	Código GMDN	Código EMDN	Fabricante (nombre y dirección)	SRN (número de registro único) del fabricante
ET	GMDN-kood	EMDN-kood	Tootja (nimi ja aadress)	Tootja unikaalne registreerimisnumber
FR	Code GMDN	Code EMDN	Fabricant (nom et adresse)	Numéro d'enregistrement unique du fabricant
HR	GMDN kod	EMDN kod	Proizvođač (naziv i adresa)	SRN (jedinstveni registracijski broj) proizvođača
HU	GMDN-kód	EMDN-kód	Gyártó (név és cím)	Gyártó egyedi regisztrációs száma (SRN)
IT	Codice GMDN	Codice EMDN	Fabbricante (nome e indirizzo)	SRN (numero di registrazione unico) del fabbricante
LV	GMDN kods	EMDN kods	Ražotājs (nosaukums un adrese)	Ražotāja vienotais reģistrācijas numurs (VRN)
LT	Visuotinės medicinos priemonių nomenklatūros kodas	Europos medicinos priemonių nomenklatūros kodas	Gamintojas (pavadinimas ir adresas)	Gamintojo unikalusis registracijos numeris
NO	GMDN-kode	EMDN-kode	Produsent (navn og adresse)	Produsentens SRN
PL	Kod GMDN	Kod Europejskiej Nomenklatury Wyrobów Medycznych	Producent (nazwa i adres)	Niepowtarzalny numer rejestracyjny producenta
PT	Código GMDN	Código EMDN	Fabricante (Nome e Morada)	Número único de registo do fabricante
RO	Cod GMDN	Cod EMDN	Producător (nume și adresă)	SRN producător
SK	Kód GMDN	Kód EMDN	Výrobca (Názov a adresa)	Jediné registračné číslo (SRN) výrobcu
SV	GMDN-kod	EMDN-kod	Tillverkare (namn och adress)	Tillverkarens SRN
TR	GMDN Kodu	EMDN Kodu	Üretici (İsim ve Adres)	Üretici SRN'si

EN	Authorized Representative (Name and Address)	Authorized Representative SRN	Produced by (Site of Manufacture) (Name and Address)
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)
CS	Zplnomocněný zástupce (název a adresa)	Jediné registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fabrikationssted) (Navn og adresse)
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Ονομασία και Διεύθυνση)
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootnud (tootmiskoht) (nimi ja aadress)
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)
LT	Įgaliotasis atstovas (pavadinimas ir adresas)	Įgaliotojo atstovo unikalusis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)
RO	Reprezentant autorizat (nume și adresă)	SRN reprezentant autorizat	Produs de către (locație producție) (nume și adresă)
SK	Autorizovaný zástupca (názov a adresa)	Jediné registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)

EN	Conformity Assessment Procedure	Annex II and III	Full Name
BG	Процедура за оценка на съответствието	Приложение II и III	Пълно наименование
CS	Postup posuzování shody	Příloha II a III	Celý název
DA	Overensstemmelsesvurderingsprocedure	Bilag II og III	Fulde navn
DE	Konformitätsbewertungsverfahren	Anhang II und III	Vollständiger Name
EL	Διαδικασία αξιολόγησης συμμόρφωσης	Παράρτημα II και III	Πλήρης ονομασία
ES	Procedimiento de evaluación de la conformidad	Anexos II y III	Nombre completo
ET	Vastavushindamismenetlus	II ja III lisa	Täisnimi
FR	Procédure d'évaluation de la conformité	Annexes II et III	Nom complet
HR	Postupak ocjenjivanja sukladnosti	Prilog II. i III.	Puni naziv
HU	Megfelelőségértékelési eljárás	II. és III. melléklet	Teljes név
IT	Procedura di valutazione della conformità	Allegati II e III	Nome completo
LV	Atbilstības novērtēšanas procedūra	II un III pielikums	Pilns nosaukums
LT	Atitikties vertinimo procedūra	II ir III priedai	Vardas ir pavardė
NO	Framgangsmåte for samsvarsvurdering	Vedlegg II og III	Fullt navn
PL	Procedura oceny zgodności	Załącznik II oraz III	Imię i nazwisko
PT	Procedimento de avaliação da conformidade	Anexo II e III	Nome completo
RO	Procedură de evaluare a conformității	Anexa II și III	Numele complet
SK	Postup posudzovania zhody	Príloha II a III	Celý názov
SV	Förfarande för bedömning av överensstämmelse	Bilaga II och III	Fullständigt namn
TR	Uygunluk Değerlendirme Prosedürü	Ek II ve III	Adı Soyadı

EN	Function	Signed for, and on behalf of	Date Issued
BG	Длъжност	Подписано за и от името на	Дата на издаване
CS	Funkce	Podepsáno za a jménem	Datum vydání
DA	Funktion	Underskrevet for og på vegne af	Udstedelsesdato
DE	Funktion	Unterzeichnet für und im Auftrag von	Datum
EL	Λειτουργία	Υπογράφεται για και εκ μέρους του/της	Ημερομηνία έκδοσης
ES	Función	Firmada por, y en nombre de	Fecha
ET	Funktsioon	Alla kirjutanud (kelle poolt ja nimel)	Väljaandmise kuupäev
FR	Fonction	Signé par et au nom de	Date d'établissement
HR	Funkcija	Potpisano za i u ime	Datum izdavanja
HU	Beosztás	Aláíró a következő képviseletében és nevében	Kiadás dátuma
IT	Funzione	Firmato a nome e per conto di	Data di rilascio
LV	Amats	Parakstīts šādas personas vārdā	Izdošanas datums
LT	Pareigos	Subjekto, kurio vardu pasirašoma, pavadinimas	Išdavimo data
NO	Funksjon	Signert for, og på vegne av	Utstedelsesdato
PL	Funkcja	Podpisano w imieniu	Data wydania
PT	Função	Assinado e em nome de	Data de emissão
RO	Funcția	Semnat pentru și în numele	Data eliberării
SK	Funkcia	Podpísané za a v mene	Dátum vydania
SV	Funktion	Undertecknat för och på uppdrag av	Datum för utfärdande
TR	Görevi	Namına ve temsilen imza	Düzenlenme Tarihi

EN	Supersedes	Signature	Date of Approval
BG	Замества	Подпис	Дата на одобрение
CS	Nahrazuje	Podpis	Datum schválení
DA	Erstatter	Underskrift	Godkendelsesdato
DE	Ersetzt	Unterschrift	Datum der Genehmigung
EL	Αντικαθιστά	Υπογραφή	Ημερομηνία έγκρισης
ES	Sustituye	Firma	Fecha de aprobación
ET	Asendab	Allkiri	Heakskiitmise kuupäev
FR	Annule et remplace	Signature	Date de l'autorisation
HR	Zamjenjuje	Potpis	Datum odobrenja
HU	Hatálytalanítja a következő dokumentumot:	Aláírás	Jóváhagyás dátuma
IT	Sostituisce	Firma	Data di approvazione
LV	Aizstāj	Paraksts	Apstiprināšanas datums
LT	Pakeičia	Parašas	Patvirtinimo data
NO	Erstatter	Signatur	Godkjenningsdato
PL	Zastępuje	Podpis	Data zatwierdzenia
PT	Substitui	Assinatura	Data de aprovação
RO	Înlocuitor	Semnătură	Data aprobării
SK	Nahrádza	Podpis	Dátum schválenia
SV	Ersätter	Namnteckning	Datum för godkännande
TR	Yerini aldığı belge	İmza	Onay Tarihi

EN	Place Issued	Effective (Date or Lot Number)
BG	Място на издаване	В сила от/за (дата или номер на партида)
CS	Místo vydání	Účinné od (datum nebo číslo šarže)
DA	Udstedelsessted	Ikrafttrædelse (dato eller lotnummer)
DE	Ort	Gültig ab (Datum oder Chargenbezeichnung)
EL	Τόπος έκδοσης	Σε ισχύ από (Ημερομηνία ή αρ. παρτίδας)
ES	Expedida en	Efectiva (fecha o número de lote)
ET	Väljaandmise koht	Jõustumine (kuupäev või partiinumber)
FR	Lieu d'établissement	Entrée en vigueur (date ou numéro de lot)
HR	Mjesto izdavanja	Stupa na snagu (datum ili broj serije)
HU	Kiadás helye	Hatálybalépés (dátum vagy tételszám)
IT	Luogo di rilascio	Valido da (data o numero di lotto)
LV	Izdošanas vieta	Spēkā no (datums vai partijas numurs)
LT	Išdavimo vieta	Įsigalioja (data arba partijos numeris)
NO	Utstedelsessted	Gjelder fra (dato eller lotnummer)
PL	Miejsce wydania	Obowiązuje od (data lub numer partii)
PT	Local de emissão	Efetividade (Data ou número de lote)
RO	Locul eliberării	Valabilitate (data sau numărul lotului)
SK	Miesto vydania	Účinnosť od (dátum alebo číslo šarže)
SV	Plats för utfärdande	Verkställigt (datum eller lotnummer)
TR	Düzenlendiği Yer	Yürürlük (Tarih veya Lot Numarası)

EN	**We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.** **This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.**
BG	Ние, долуподписаните, с настоящото декларираме, че гореописаното(ите) медицинско(и) изделие(я) за инвитро диагностика отговаря(т) на приложимите разпоредби на Регламент (ЕС) 2017/746 на Европейския парламент и на Съвета от 5 април 2017 г. относно медицинските изделия за инвитро диагностика; освен това отговаря(т) на приложимите разпоредби на Директива 2011/65/ЕС на Европейския парламент и на Съвета от 8 юни 2011 г. относно ограничението на употребата на определени опасни вещества в електрическото и електронното оборудване и на приложимите разпоредби на Директива 2006/42/ЕО на Европейския парламент и на Съвета от 17 май 2006 г. относно машините, и за изменение на Директива 95/16/ЕО, както е транспонирана в националното законодателство на държавите членки. Тази декларация се прави в съответствие с Приложение IV на Регламента за IVD, Приложение VI на Директивата за ограничаване на опасните вещества (ROHS) и Приложение II на Директивата относно машините и за нейното издаване отговорност носи единствено производителят.
CS	My, níže podepsaní, tímto prohlašujeme, že diagnostický(-é) zdravotnický(-é) prostředek (prostředky) in vitro uvedený(-é) výše je (jsou) ve shodě s příslušnými ustanoveními nařízení Evropského parlamentu a Rady (EU) 2017/746 ze dne 5. dubna 2017 o diagnostických zdravotnických prostředcích in vitro; a že je (jsou) dále ve shodě s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2011/65/EU ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních a s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2006/42/ES ze dne 17. května 2006 o strojních zařízeních a o změně směrnice 95/16/ES, jak byla provedena ve vnitrostátním právu členských států. Toto prohlášení je v souladu s Přílohou IV nařízení IVD, Přílohou VI směrnice ROHS a Přílohou II směrnice o strojních zařízeních a je vydáno na výhradní odpovědnost výrobce.
DA	Vi, undertegnede, erklærer herved, at det in vitro-diagnostiske medicinske udstyr, der er beskrevet ovenfor, er i overensstemmelse med de gældende bestemmelser i Europa-Parlamentets og Rådets forordning (EU) 2017/746 af 5. april 2017 om in vitro-diagnostisk medicinsk udstyr, ligesom det overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2011/65/EU af 8. juni 2011 om begrænsning af brugen af visse farlige stoffer i elektrisk og elektronisk udstyr samt overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2006/42/EF af 17. maj 2006 om maskiner og ændring af direktiv 95/16/EF, som det er transponeret i medlemsstaternes lovgivning. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV, ROHS-direktivets bilag VI samt maskindirektivets bilag II og udstedes under fabrikantens eneansvar.
DE	Wir, die Unterzeichner, erklären hiermit, dass das oben beschriebene In-vitro-Diagnostikum/die oben beschriebenen In-vitro-Diagnostika die entsprechenden Bestimmungen der Verordnung (EU) 2017/746 des Europäischen Parlaments und des Rates vom 5. April 2017 über In-vitro-Diagnostika erfüllen und zusätzlich die entsprechenden Bestimmungen der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten sowie der Richtlinie 2006/42/EG des Europäischen Parlaments und des Rates vom 17. Mai 2006 über Maschinen und zur Änderung der Richtlinie 95/16/EG gemäß Umsetzung in den Gesetzen der Mitgliedsstaaten. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung, Anhang VI der RoHS-Richtlinie und Anhang II der Maschinen-Richtlinie und wird unter alleiniger Verantwortung des Herstellers ausgestellt.
EL	Εμείς, οι υπογράφοντες, δηλώνουμε με το παρόν ότι τα προαναφερόμενα διαγνωστικά ιατροτεχνολογικά προϊόντα συμμορφώνονται με τις ισχύουσες διατάξεις του Κανονισμού (ΕΕ) 2017/746 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 5ης Απριλίου 2017 σχετικά με τα in vitro διαγνωστικά ιατροτεχνολογικά προϊόντα και επίσης συμμορφώνονται με τις ισχύουσες διατάξεις της Οδηγίας 2011/65/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 8ης Ιουνίου 2011 σχετικά με τους περιορισμούς στη χρήση συγκεκριμένων επικίνδυνων ουσιών στον ηλεκτρικό και ηλεκτρονικό εξοπλισμό, καθώς και με τις ισχύουσες διατάξεις της Οδηγίας 2006/42/ΕΚ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 17ης Μαΐου 2006 σχετικά με τον μηχανικό εξοπλισμό και την τροποποιητική Οδηγία 95/16/ΕΚ όπως αυτή μεταφέρθηκε στη νομοθεσία των κρατών μελών. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD, το Παράρτημα VI της Οδηγίας ROHS και το Παράρτημα II της Οδηγίας για τον μηχανικό εξοπλισμό και εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή.
ES	Nosotros, los abajo firmantes, por la presente declaramos que el(los) producto(s) sanitario(s) para diagnóstico *in vitro* descrito(s) anteriormente cumple(n) las disposiciones aplicables del reglamento (UE) 2017/746 del Parlamento Europeo y del Consejo del 5 de abril de 2017 sobre productos sanitarios para diagnóstico *in vitro*; y además cumple(n) las disposiciones aplicables de la Directiva 2011/65/EU del Parlamento Europeo y del Consejo del 8 de junio de 2011 sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos, y las disposiciones aplicables de la Directiva 2006/42/EC del Parlamento Europeo y del Consejo del 17 de mayo de 2006 sobre maquinaria, y la Directiva de enmienda 95/16/EC tal y como se ha incorporado en las leyes de los Estados Miembros. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD, Anexo VI de la Directiva ROHS y Anexo II de la Directiva de máquinas y es emitida bajo la exclusiva responsabilidad del fabricante.
ET	Meie, allakirjutanud, kinnitame, et eespool kirjeldatud *in vitro* diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (*in vitro* diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele ning lisaks vastab see kohaldatavatele sätetele Euroopa Parlamendi ja nõukogu 8. juuni 2011. aasta direktiivis 2011/65/EL (teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes) ja Euroopa Parlamendi ja nõukogu direktiivis 2006/42/EÜ, 17. mai 2006, mis käsitleb masinaid ja millega muudetakse direktiivi 95/16/EÜ, nagu see on üle võetud liikmesriikide seadustesse. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale, ROHS direktiivi VI lisale ja masinadirektiivi II lisale ning see on välja antud tootja vastutusel.
FR	Nous soussigné(e)s, déclarons par la présente que le(s) dispositif(s) médical(aux) de diagnostic *in vitro* indiqué(s) ci-dessus est/sont conforme(s) aux dispositions applicables du Règlement (UE) 2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic *in vitro*, aux dispositions applicables de la Directive 2011/65/UE du Parlement européen et du Conseil du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques, aux dispositions applicables de la Directive 2006/42/CE du Parlement européen et du Conseil du 17 mai 2006 relative aux machines et modifiant la Directive 95/16/CE, telles que transposées dans le droit national des États membres. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV, à l'Annexe VI de la Directive ROHS ainsi qu'à l'Annexe II de la Directive Machines sous la seule responsabilité du fabricant.
HR	Mi, niže potpisani, ovim putem izjavljujemo da su gore navedeni *in vitro* dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o *in vitro* dijagnostičkim medicinskim proizvodima; i dodatno primjenjivim odredbama Direktive 2011/65/EU Europskog parlamenta i Vijeća od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi, te primjenjivim odredbama Direktive 2006/42/EZ Europskog parlamenta i Vijeća od 17. svibnja 2006. o strojevima zamjenjujući Direktivu 95/16/EZ kako je pretočeno u zakone država članica. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD, Prilogom VI. Direktive ROHS i Prilogom II. Direktive o strojevima i izdaje se pod isključivom odgovornošću proizvođača.
HU	Alulírottak ezennel kijelentjük, hogy a fent leírt in vitro orvostechnikai eszköz(ök) megfelel(nek) az Európai Parlament és a Tanács in vitro diagnosztikai orvostechnikai eszközökről szóló (EU) 2017/746 (2017. április 5.) rendelete vonatkozó rendelkezéseit; továbbá az Európai Parlament és a Tanács egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról szóló 2011/65/EU (2011. június 8.) irányelve (RoHS irányelv) vonatkozó rendelkezéseit; valamint az Európai Parlament és a Tanács a gépekről és a 95/16/EK irányelv módosításáról szóló 2006/42/EK (2006. május 17.) irányelve vonatkozó rendelkezéseit a tagállamok jogrendjébe átültető rendelkezéseknek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében, a RoHS irányelv VI. mellékletében és a gépekről szóló irányelv II. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.

EN	**We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.** **This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.**
IT	Noi, i sottoscritti, con la presente dichiariamo che il(i) dispositivo(i) medico-diagnostico(i) *in vitro* sopra descritto(i) è(sono) conforme(i) alle disposizioni applicabili del regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medico-diagnostici *in vitro*; è(sono) inoltre conforme(i) alle disposizioni applicabili della direttiva 2011/65/UE del Parlamento europeo e del Consiglio dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche, e alle disposizioni applicabili della direttiva 2006/42/CE del Parlamento europeo e del Consiglio del 17 maggio 2006 relativa alle macchine e che modifica la direttiva 95/16/CE come recepite nelle legislazioni degli Stati membri. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD, all'allegato VI della direttiva ROHS e all'allegato II della direttiva macchine ed è rilasciata sotto la responsabilità esclusiva del fabbricante.
LV	Mēs, apakšā parakstījušies, ar šo paziņojam, ka iepriekš aprakstītā(-s) *in vitro* diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par *in vitro* diagnostikas medicīniskām ierīcēm un papildus prasībām, kas noteiktas Eiropas Parlamenta un Padomes Direktīvā 2011/65/ES (2011. gada 8. jūnijs) par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās un Eiropas Parlamenta un Padomes Direktīvā 2006/42/EK (2006. gada 17. maijs) par mašīnām, un ar kuru groza Direktīvu 95/16/EK, kā tā ieviesta dalībvalstu tiesību aktos. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu, ROHS direktīvas VI pielikumu un Direktīvas par mašīnām II pielikumu un par izdošanu atbild vienīgi ražotājs.
LT	Mes, toliau pasirašiusieji (-iusiosios), pareiškiame, kad anksčiau minėta (-os) *in vitro* diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl *in vitro* diagnostikos medicinos priemonių taikytinas nuostatas; taip pat ji (jos) atitinka 2011 m. birželio 8 d. Europos Parlamento ir Tarybos direktyvos 2011/65/ES dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo taikomas nuostatas ir 2006 m. gegužės 17 d. Europos Parlamento ir Tarybos direktyvos 2006/42/EB dėl mašinų, iš dalies keičiančios Direktyvą 95/16/EB, taikomas nuostatas, perkeltas į valstybių narių teisės aktus. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu, ROHS direktyvos VI priedu ir Mašinų direktyvos II priedu ir yra išduodama tik gamintojo atsakomybe.
NO	Vi, undertegnede, erklærer herved at utstyret til *in vitro*-diagnostikk som er anført ovenfor, er i samsvar med gjeldende bestemmelser i Europaparlaments- og rådsforordning (EU) 2017/746 av 5. april 2017 om medisinsk utstyr til *in vitro*-diagnostikk, og ytterligere overholder gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2011/65/EU av 8. juni 2011 om bruksbegrensninger av visse farlige stoffer i elektrisk og elektronisk utstyr, og til gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2006/42/EF av 17. mai 2006 om maskiner, og endring av direktiv 95/16/EF som innarbeidet i medlemsstatenes lovgivning. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen, vedlegg VI i ROHS-direktivet og vedlegg II i maskindirektivet og er utstedt under produsentens eneansvar.
PL	My, niżej podpisani, niniejszym oświadczamy, że wymieniony(-e) powyżej wyrób(wyroby) medyczny(-e) do diagnostyki in vitro spełnia(-ją) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki in vitro, a ponadto wymagania Dyrektywy 2011/65/UE Parlamentu Europejskiego i Rady z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym, Dyrektywy 2006/42/WE Parlamentu Europejskiego i Rady z dnia 17 maja 2006 r. w sprawie maszyn, zmieniającej Dyrektywę 95/16/WE, w sposób, w jaki zostały one wdrożone do ustawodawstwa państw członkowskich. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR, Załącznikiem VI Dyrektywy ROHS oraz Załącznikiem II Dyrektywy Maszynowej i wydana na wyłączną odpowiedzialność producenta.
PT	Nós, abaixo assinados, declaramos que os dispositivos médicos para diagnóstico *in vitro* descritos acima estão em conformidade com as disposições aplicáveis do Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho, de 5 de abril de 2017, relativo aos dispositivos médicos para diagnóstico *in vitro*; e adicionalmente, em conformidade com as disposições aplicáveis da Diretiva 2011/65/UE do Parlamento Europeu e do Conselho, de 8 de junho de 2011, relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrónicos, e com as disposições aplicáveis da Diretiva 2006/42/CE do Parlamento Europeu e do Conselho, de 17 de maio de 2006, sobre máquinas e que altera a Diretiva 95/16/CE, conforme transposta nas leis dos Estados membros. Esta declaração é feita de acordo com o Anexo IV do Regulamento IVD, o Anexo VI da Diretiva ROHS e o Anexo II da Diretiva relativa às Máquinas e é emitida sob a exclusiva responsabilidade do fabricante.
RO	Subsemnații, declarăm că dispozitivul (dispozitivele) medical(e) pentru diagnostic in vitro descrise mai sus sunt conforme cu dispozițiile aplicabile din Regulamentul (UE) 2017/746 al Parlamentului European și al Consiliului din 5 aprilie 2017 privind Dispozitivele medicale pentru diagnosticul in vitro; și, în plus, respectă dispozițiile aplicabile din Directiva 2011/65/UE a Parlamentului European și a Consiliului din 8 iunie 2011 privind restricția utilizării anumitor substanțe periculoase în echipamentele electrice și electronice și cu dispozițiile aplicabile din Directiva 2006/42/CE a Parlamentului European și a Consiliului din 17 mai 2006 privind utilajele și modificarea Directivei 95/16/CE, transpusă în legile statelor membre. Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD, anexa VI la Directiva ROHS și anexa II la Directiva utilajelor și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpísaní, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) in vitro uvedená(-é) vyššie je (sú) v zhode s príslušnými ustanoveniami Nariadenia Európskeho parlamentu a Rady (EÚ) 2017/746 z 5. apríla 2017 o diagnostických zdravotnických pomôckach in vitro; a že je (sú) ďalej v zhode s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2011/65/EÚ z 8. júna 2011 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach a s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2006/42/ES zo 17. mája 2006 o strojových zariadeniach a o zmene a doplnení Smernice 95/16/ES tak, ako boli transponované do zákonov členských štátov. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD, Prílohou VI k Smernici ROHS a Prílohou II k Smernici o strojových zariadeniach a vydáva sa na výhradnú zodpovednosť výrobcu.
SV	Vi, undertecknade, försäkrar härmed att den eller de medicintekniska produkter för *in vitro*-diagnostik som beskrivs ovan överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets förordning (EU) 2017/746 av den 5 april 2017 om medicintekniska produkter för *in vitro*-diagnostik samt även överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning samt med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2006/42/EG av den 17 maj 2006 om maskiner och om ändring av direktiv 95/16/EG (omarbetning) som införlivats i medlemsstaternas lagstiftning. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen, bilaga VI till ROHS-direktivet samt bilaga II till maskindirektivet och utfärdas under tillverkarens enskilda ansvar.
TR	Biz, aşağıda imzaları bulunan, yukarıda belirtilen in vitro diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli İn Vitro Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu ve ayrıca elektrikli ve elektronik cihazlarda belirli tehlikeli maddelerin kullanımının sınırlandırılmasına ilişkin 8 Haziran 2011 tarihli Konseyin ve 2011/65/EU sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine, makinelere ilişkin 17 Mayıs 2006 tarihli Konseyin ve 2006/42/EC sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine ve üye devlet yasalarına aktarılan 95/16/EC sayılı ek Direktife uygun olduğunu beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV, ROHS Direktifi Ek VI ve Makineler Direktifi Ek II uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altında yayınlanmıştır.

End of form

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0004FU
Basic UDI-DI Name: Alkaline Wash
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
9D31-20	Alkaline Wash	58236	W0201010185

Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 USA
Manufacturer SRN	US-MF-000017777
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	Fisher Diagnostics 8365 Valley Pike Middletown VA 22645 USA
Conformity Assessment Procedure	**Annex II and III**

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

Full Name: Thomas Creel
Function: Sr. Director, Instrument and Automation Quality
Signature: Thomas Creel
Date of Approval: 20-May-2022

Full Name: Michele Smith-Waheed
Function: Associate Director, Regulatory Affairs
Signature: M Smith-Waheed
Date of Approval: 20-May-2022

Signed for, and on behalf of: Abbott Laboratories, 1915 Hurd Drive, Irving, TX 75038

Date Issued: 20-May-2022
Supersedes: N/A

Place Issued: Irving, Texas
Effective (Date or Lot Number): 20-May-2022

EN	EU Declaration of Conformity	Basic UDI-DI	Basic UDI-DI Name
BG	ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ	Базов UDI-DI	Наименование на базов UDI-DI
CS	EU PROHLÁŠENÍ O SHODĚ	Základní UDI-DI	Název základního UDI-DI
DA	EU-OVERENSSTEMMELSESERKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄTSERKLÄRUNG	Basis-UDI-DI	Basis-UDI-DI Name
EL	ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ	Βασικό UDI-DI	Ονομασία βασικού UDI-DI
ES	DECLARACIÓN UE DE CONFORMIDAD	UDI-DI Básico	Nombre UDI-DI Básico
ET	ELi vastavusdeklaratsioon	Põhi-UDI-DI	Põhi-UDI-DI nimi
FR	Déclaration de conformité UE	IUD-ID de base	Nom IUD-ID de base
HR	EU IZJAVA O SUKLADNOSTI	Osnovni UDI-DI	Naziv osnovnog UDI-DI
HU	EU-MEGFELELŐSÉGI NYILATKOZAT	Alapvető UDI-DI	Alapvető UDI-DI neve
IT	Dichiarazione di conformità UE	UDI-DI di base	Nome UDI-DI di base
LV	ES atbilstības deklarācija	Pamata UDI-DI	Pamata UDI-DI nosaukums
LT	ES ATITIKTIES DEKLARACIJA	Bazinis UDI-DI	Bazinio UDI-DI pavadinimas
NO	EU-samsvarserklæring	Grunnleggende UDI-DI	Grunnleggende UDI-DI-navn
PL	DEKLARACJA ZGODNOŚCI UE	Kod Basic UDI-DI	Nazwa kodu Basic UDI-DI
PT	DECLARAÇÃO UE DE CONFORMIDADE	UDI-DI básico	Nome UDI-DI Básico
RO	Declarația de Conformitate UE	UDI-DI de bază	Nume UDI-DI de bază
SK	EÚ VYHLÁSENIE O ZHODE	Základný UDI-DI	Názov základného UDI-DI
SV	EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE	Grundläggande UDI-DI	Namn på grundläggande UDI-DI
TR	AB Uygunluk Beyanı	Temel UDI-DI	Temel UDI-DI İsmi

EN	Risk Class	List Number and Size Code	Product and Trade Name
BG	Клас според риска	Каталожен номер и код на размера	Име на продукта и търговско наименование
CS	Riziková třída	Katalogové číslo a koncové dvojčíslí určující velikost soupravy	Název produktu a obchodní název
DA	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og varemærkenavn
DE	Risikoklasse	Bestellnummer und Größencode	Produkt- und Handelsname
EL	Κατηγορία κινδύνου	Κωδικός Προϊόντος και Κωδικός Συσκευασίας	Προϊόν και Εμπορική Ονομασία
ES	Clase de riesgo	Número de referencia y código de tamaño	Producto y marca comercial
ET	Riskiklass	Katalooginumber ja suurusekood	Toote nimetus ja kaubanimi
FR	Classe de risque	Référence	Nom de produit et de marque
HR	Klasa rizika	Kataloški broj i oznaka pakiranja	Naziv proizvoda i zaštićeni naziv
HU	Kockázati osztály	Listaszám és készletkiszerelés-kód	Termék- és kereskedelmi név
IT	Classe di rischio	Numero di listino e codice formato	Prodotto e nome commerciale
LV	Riska klase	Kataloga numurs un izmēra kods	Produkta nosaukums un tirdzniecības nosaukums
LT	Rizikos klasė	Katalogo numeris ir dydžio kodas	Gaminio ir prekybinis pavadinimai
NO	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og handelsnavn
PL	Klasa ryzyka	Numer katalogowy	Nazwa produktu i nazwa handlowa
PT	Classe de risco	Número de lista e código de apresentação	Produto e nome comercial
RO	Clasă de risc	Număr de listă și cod dimensiune	Denumirea produsului și denumirea comercială
SK	Riziková trieda	Katalógové číslo	Názov produktu a obchodný názov
SV	Riskklass	Listnummer och storlekskod	Produkt och firmanamn
TR	Risk Sınıfı	Liste Numarası ve Boyut Kodu	Ürün ve Ticari İsmi

EN	GMDN Code	EMDN Code	Manufacturer (Name and Address)	Manufacturer SRN
BG	Код GMDN	Код EMDN	Производител (име и адрес)	ЕРН на производителя
CS	Kód GMDN	Kód EMDN	Výrobce (název a adresa)	Jediné registrační číslo výrobce
DA	GMDN-kode	EMDN-kode	Fabrikant (navn og adresse)	Fabrikants SRN
DE	GMDN-Code	EMDN-Code	Hersteller (Name und Adresse)	Hersteller-SRN
EL	Κωδικός GMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κωδικός EMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κατασκευαστής (Όνομα και Διεύθυνση)	SRN (Μοναδικός Αριθμός Μητρώου) Κατασκευαστή
ES	Código GMDN	Código EMDN	Fabricante (nombre y dirección)	SRN (número de registro único) del fabricante
ET	GMDN-kood	EMDN-kood	Tootja (nimi ja aadress)	Tootja unikaalne registreerimisnumber
FR	Code GMDN	Code EMDN	Fabricant (nom et adresse)	Numéro d'enregistrement unique du fabricant
HR	GMDN kod	EMDN kod	Proizvođač (naziv i adresa)	SRN (jedinstveni registracijski broj) proizvođača
HU	GMDN-kód	EMDN-kód	Gyártó (név és cím)	Gyártó egyedi regisztrációs száma (SRN)
IT	Codice GMDN	Codice EMDN	Fabbricante (nome e indirizzo)	SRN (numero di registrazione unico) del fabbricante
LV	GMDN kods	EMDN kods	Ražotājs (nosaukums un adrese)	Ražotāja vienotais reģistrācijas numurs (VRN)
LT	Visuotinės medicinos priemonių nomenklatūros kodas	Europos medicinos priemonių nomenklatūros kodas	Gamintojas (pavadinimas ir adresas)	Gamintojo unikalusis registracijos numeris
NO	GMDN-kode	EMDN-kode	Produsent (navn og adresse)	Produsentens SRN
PL	Kod GMDN	Kod Europejskiej Nomenklatury Wyrobów Medycznych	Producent (nazwa i adres)	Niepowtarzalny numer rejestracyjny producenta
PT	Código GMDN	Código EMDN	Fabricante (Nome e Morada)	Número único de registo do fabricante
RO	Cod GMDN	Cod EMDN	Producător (nume și adresă)	SRN producător
SK	Kód GMDN	Kód EMDN	Výrobca (Názov a adresa)	Jediné registračné číslo (SRN) výrobcu
SV	GMDN-kod	EMDN-kod	Tillverkare (namn och adress)	Tillverkarens SRN
TR	GMDN Kodu	EMDN Kodu	Üretici (İsim ve Adres)	Üretici SRN'si

EN	Authorized Representative (Name and Address)	Authorized Representative SRN	Produced by (Site of Manufacture) (Name and Address)
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)
CS	Zplnomocněný zástupce (název a adresa)	Jediné registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fabrikationssted) (Navn og adresse)
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Ονομασία και Διεύθυνση)
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootnud (tootmiskoht) (nimi ja aadress)
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)
LT	Įgaliotasis atstovas (pavadinimas ir adresas)	Įgaliotojo atstovo unikalusis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)
RO	Reprezentant autorizat (nume și adresă)	SRN reprezentant autorizat	Produs de către (locație producție) (nume și adresă)
SK	Autorizovaný zástupca (názov a adresa)	Jediné registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)

EN	Conformity Assessment Procedure	Annex II and III	Full Name
BG	Процедура за оценка на съответствието	Приложение II и III	Пълно наименование
CS	Postup posuzování shody	Příloha II a III	Celý název
DA	Overensstemmelsesvurderingsprocedure	Bilag II og III	Fulde navn
DE	Konformitätsbewertungsverfahren	Anhang II und III	Vollständiger Name
EL	Διαδικασία αξιολόγησης συμμόρφωσης	Παράρτημα II και III	Πλήρης ονομασία
ES	Procedimiento de evaluación de la conformidad	Anexos II y III	Nombre completo
ET	Vastavushindamismenetlus	II ja III lisa	Täisnimi
FR	Procédure d'évaluation de la conformité	Annexes II et III	Nom complet
HR	Postupak ocjenjivanja sukladnosti	Prilog II. i III.	Puni naziv
HU	Megfelelőségértékelési eljárás	II. és III. melléklet	Teljes név
IT	Procedura di valutazione della conformità	Allegati II e III	Nome completo
LV	Atbilstības novērtēšanas procedūra	II un III pielikums	Pilns nosaukums
LT	Atitikties vertinimo procedūra	II ir III priedai	Vardas ir pavardė
NO	Framgangsmåte for samsvarsvurdering	Vedlegg II og III	Fullt navn
PL	Procedura oceny zgodności	Załącznik II oraz III	Imię i nazwisko
PT	Procedimento de avaliação da conformidade	Anexo II e III	Nome completo
RO	Procedură de evaluare a conformității	Anexa II și III	Numele complet
SK	Postup posudzovania zhody	Príloha II a III	Celý názov
SV	Förfarande för bedömning av överensstämmelse	Bilaga II och III	Fullständigt namn
TR	Uygunluk Değerlendirme Prosedürü	Ek II ve III	Adı Soyadı

EN	Function	Signed for, and on behalf of	Date Issued
BG	Длъжност	Подписано за и от името на	Дата на издаване
CS	Funkce	Podepsáno za a jménem	Datum vydání
DA	Funktion	Underskrevet for og på vegne af	Udstedelsesdato
DE	Funktion	Unterzeichnet für und im Auftrag von	Datum
EL	Λειτουργία	Υπογράφεται για και εκ μέρους του/της	Ημερομηνία έκδοσης
ES	Función	Firmada por, y en nombre de	Fecha
ET	Funktsioon	Alla kirjutanud (kelle poolt ja nimel)	Väljaandmise kuupäev
FR	Fonction	Signé par et au nom de	Date d'établissement
HR	Funkcija	Potpisano za i u ime	Datum izdavanja
HU	Beosztás	Aláíró a következő képviseletében és nevében	Kiadás dátuma
IT	Funzione	Firmato a nome e per conto di	Data di rilascio
LV	Amats	Parakstīts šādas personas vārdā	Izdošanas datums
LT	Pareigos	Subjekto, kurio vardu pasirašoma, pavadinimas	Išdavimo data
NO	Funksjon	Signert for, og på vegne av	Utstedelsesdato
PL	Funkcja	Podpisano w imieniu	Data wydania
PT	Função	Assinado e em nome de	Data de emissão
RO	Funcția	Semnat pentru și în numele	Data eliberării
SK	Funkcia	Podpísané za a v mene	Dátum vydania
SV	Funktion	Undertecknat för och på uppdrag av	Datum för utfärdande
TR	Görevi	Namına ve temsilen imza	Düzenlenme Tarihi

EN	Supersedes	Signature	Date of Approval
BG	Замества	Подпис	Дата на одобрение
CS	Nahrazuje	Podpis	Datum schválení
DA	Erstatter	Underskrift	Godkendelsesdato
DE	Ersetzt	Unterschrift	Datum der Genehmigung
EL	Αντικαθιστά	Υπογραφή	Ημερομηνία έγκρισης
ES	Sustituye	Firma	Fecha de aprobación
ET	Asendab	Allkiri	Heakskiitmise kuupäev
FR	Annule et remplace	Signature	Date de l'autorisation
HR	Zamjenjuje	Potpis	Datum odobrenja
HU	Hatálytalanítja a következő dokumentumot:	Aláírás	Jóváhagyás dátuma
IT	Sostituisce	Firma	Data di approvazione
LV	Aizstāj	Paraksts	Apstiprināšanas datums
LT	Pakeičia	Parašas	Patvirtinimo data
NO	Erstatter	Signatur	Godkjenningsdato
PL	Zastępuje	Podpis	Data zatwierdzenia
PT	Substitui	Assinatura	Data de aprovação
RO	Înlocuitor	Semnătură	Data aprobării
SK	Nahrádza	Podpis	Dátum schválenia
SV	Ersätter	Namnteckning	Datum för godkännande
TR	Yerini aldığı belge	İmza	Onay Tarihi

EN	Place Issued	Effective (Date or Lot Number)
BG	Място на издаване	В сила от/за (дата или номер на партида)
CS	Místo vydání	Účinné od (datum nebo číslo šarže)
DA	Udstedelsessted	Ikrafttrædelse (dato eller lotnummer)
DE	Ort	Gültig ab (Datum oder Chargenbezeichnung)
EL	Τόπος έκδοσης	Σε ισχύ από (Ημερομηνία ή αρ. παρτίδας)
ES	Expedida en	Efectiva (fecha o número de lote)
ET	Väljaandmise koht	Jõustumine (kuupäev või partiinumber)
FR	Lieu d'établissement	Entrée en vigueur (date ou numéro de lot)
HR	Mjesto izdavanja	Stupa na snagu (datum ili broj serije)
HU	Kiadás helye	Hatálybalépés (dátum vagy tételszám)
IT	Luogo di rilascio	Valido da (data o numero di lotto)
LV	Izdošanas vieta	Spēkā no (datums vai partijas numurs)
LT	Išdavimo vieta	Įsigalioja (data arba partijos numeris)
NO	Utstedelsessted	Gjelder fra (dato eller lotnummer)
PL	Miejsce wydania	Obowiązuje od (data lub numer partii)
PT	Local de emissão	Efetividade (Data ou número de lote)
RO	Locul eliberării	Valabilitate (data sau numărul lotului)
SK	Miesto vydania	Účinnosť od (dátum alebo číslo šarže)
SV	Plats för utfärdande	Verkställigt (datum eller lotnummer)
TR	Düzenlendiği Yer	Yürürlük (Tarih veya Lot Numarası)

EN	**We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.** **This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.**
BG	Ние, долуподписаните, с настоящото декларираме, че гореописаното(ите) медицинско(и) изделие(я) за инвитро диагностика отговаря(т) на приложимите разпоредби на Регламент (ЕС) 2017/746 на Европейския парламент и на Съвета от 5 април 2017 г. относно медицинските изделия за инвитро диагностика; освен това отговаря(т) на приложимите разпоредби на Директива 2011/65/ЕС на Европейския парламент и на Съвета от 8 юни 2011 г. относно ограничението на употребата на определени опасни вещества в електрическото и електронното оборудване и на приложимите разпоредби на Директива 2006/42/ЕО на Европейския парламент и на Съвета от 17 май 2006 г. относно машините, и за изменение на Директива 95/16/ЕО, както е транспонирана в националното законодателство на държавите членки. Тази декларация се прави в съответствие с Приложение IV на Регламента за IVD, Приложение VI на Директивата за ограничаване на опасните вещества (ROHS) и Приложение II на Директивата относно машините и за нейното издаване отговорност носи единствено производителят.
CS	My, níže podepsaní, tímto prohlašujeme, že diagnostický(-é) zdravotnický(-é) prostředek (prostředky) in vitro uvedený(-é) výše je (jsou) ve shodě s příslušnými ustanoveními nařízení Evropského parlamentu a Rady (EU) 2017/746 ze dne 5. dubna 2017 o diagnostických zdravotnických prostředcích in vitro; a že je (jsou) dále ve shodě s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2011/65/EU ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních a s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2006/42/ES ze dne 17. května 2006 o strojních zařízeních a o změně směrnice 95/16/ES, jak byla provedena ve vnitrostátním právu členských států. Toto prohlášení je v souladu s Přílohou IV nařízení IVD, Přílohou VI směrnice ROHS a Přílohou II směrnice o strojních zařízeních a je vydáno na výhradní odpovědnost výrobce.
DA	Vi, undertegnede, erklærer herved, at det in vitro-diagnostiske medicinske udstyr, der er beskrevet ovenfor, er i overensstemmelse med de gældende bestemmelser i Europa-Parlamentets og Rådets forordning (EU) 2017/746 af 5. april 2017 om in vitro-diagnostisk medicinsk udstyr, ligesom det overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2011/65/EU af 8. juni 2011 om begrænsning af brugen af visse farlige stoffer i elektrisk og elektronisk udstyr samt overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2006/42/EF af 17. maj 2006 om maskiner og ændring af direktiv 95/16/EF, som det er transponeret i medlemsstaternes lovgivning. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV, ROHS-direktivets bilag VI samt maskindirektivets bilag II og udstedes under fabrikantens eneansvar.
DE	Wir, die Unterzeichner, erklären hiermit, dass das oben beschriebene In-vitro-Diagnostikum/die oben beschriebenen In-vitro-Diagnostika die entsprechenden Bestimmungen der Verordnung (EU) 2017/746 des Europäischen Parlaments und des Rates vom 5. April 2017 über In-vitro-Diagnostika erfüllen und zusätzlich die entsprechenden Bestimmungen der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten sowie der Richtlinie 2006/42/EG des Europäischen Parlaments und des Rates vom 17. Mai 2006 über Maschinen und zur Änderung der Richtlinie 95/16/EG gemäß Umsetzung in den Gesetzen der Mitgliedsstaaten. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung, Anhang VI der RoHS-Richtlinie und Anhang II der Maschinen-Richtlinie und wird unter alleiniger Verantwortung des Herstellers ausgestellt.
EL	Εμείς, οι υπογράφοντες, δηλώνουμε με το παρόν ότι τα προαναφερόμενα διαγνωστικά ιατροτεχνολογικά προϊόντα συμμορφώνονται με τις ισχύουσες διατάξεις του Κανονισμού (ΕΕ) 2017/746 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 5ης Απριλίου 2017 σχετικά με τα in vitro διαγνωστικά ιατροτεχνολογικά προϊόντα και επίσης συμμορφώνονται με τις ισχύουσες διατάξεις της Οδηγίας 2011/65/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 8ης Ιουνίου 2011 σχετικά με τους περιορισμούς στη χρήση συγκεκριμένων επικίνδυνων ουσιών στον ηλεκτρικό και ηλεκτρονικό εξοπλισμό, καθώς και με τις ισχύουσες διατάξεις της Οδηγίας 2006/42/ΕΚ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 17ης Μαΐου 2006 σχετικά με τον μηχανικό εξοπλισμό και την τροποποιητική Οδηγία 95/16/ΕΚ όπως αυτή μεταφέρθηκε στη νομοθεσία των κρατών μελών. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD, το Παράρτημα VI της Οδηγίας ROHS και το Παράρτημα II της Οδηγίας για τον μηχανικό εξοπλισμό και εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή.
ES	Nosotros, los abajo firmantes, por la presente declaramos que el(los) producto(s) sanitario(s) para diagnóstico *in vitro* descrito(s) anteriormente cumple(n) las disposiciones aplicables del reglamento (UE) 2017/746 del Parlamento Europeo y del Consejo del 5 de abril de 2017 sobre productos sanitarios para diagnóstico *in vitro*; y además cumple(n) las disposiciones aplicables de la Directiva 2011/65/EU del Parlamento Europeo y del Consejo del 8 de junio de 2011 sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos, y las disposiciones aplicables de la Directiva 2006/42/EC del Parlamento Europeo y del Consejo del 17 de mayo de 2006 sobre maquinaria, y la Directiva de enmienda 95/16/EC tal y como se ha incorporado en las leyes de los Estados Miembros. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD, Anexo VI de la Directiva ROHS y Anexo II de la Directiva de máquinas y es emitida bajo la exclusiva responsabilidad del fabricante.
ET	Meie, allakirjutanud, kinnitame, et eespool kirjeldatud *in vitro* diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (*in vitro* diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele ning lisaks vastab see kohaldatavatele sätetele Euroopa Parlamendi ja nõukogu 8. juuni 2011. aasta direktiivis 2011/65/EL (teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes) ja Euroopa Parlamendi ja nõukogu direktiivis 2006/42/EÜ, 17. mai 2006, mis käsitleb masinaid ja millega muudetakse direktiivi 95/16/EÜ, nagu see on üle võetud liikmesriikide seadustesse. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale, ROHS direktiivi VI lisale ja masinadirektiivi II lisale ning see on välja antud tootja vastutusel.
FR	Nous soussigné(e)s, déclarons par la présente que le(s) dispositif(s) médical(aux) de diagnostic *in vitro* indiqué(s) ci-dessus est/sont conforme(s) aux dispositions applicables du Règlement (UE) 2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic *in vitro*, aux dispositions applicables de la Directive 2011/65/UE du Parlement européen et du Conseil du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques, aux dispositions applicables de la Directive 2006/42/CE du Parlement européen et du Conseil du 17 mai 2006 relative aux machines et modifiant la Directive 95/16/CE, telles que transposées dans le droit national des États membres. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV, à l'Annexe VI de la Directive ROHS ainsi qu'à l'Annexe II de la Directive Machines sous la seule responsabilité du fabricant.
HR	Mi, niže potpisani, ovim putem izjavljujemo da su gore navedeni *in vitro* dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o *in vitro* dijagnostičkim medicinskim proizvodima; i dodatno primjenjivim odredbama Direktive 2011/65/EU Europskog parlamenta i Vijeća od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi, te primjenjivim odredbama Direktive 2006/42/EZ Europskog parlamenta i Vijeća od 17. svibnja 2006. o strojevima zamjenjujući Direktivu 95/16/EZ kako je pretočeno u zakone država članica. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD, Prilogom VI. Direktive ROHS i Prilogom II. Direktive o strojevima i izdaje se pod isključivom odgovornošću proizvođača.
HU	Alulírottak ezennel kijelentjük, hogy a fent leírt in vitro orvostechnikai eszköz(ök) megfelel(nek) az Európai Parlament és a Tanács in vitro diagnosztikai orvostechnikai eszközökről szóló (EU) 2017/746 (2017. április 5.) rendelete vonatkozó rendelkezéseit; továbbá az Európai Parlament és a Tanács egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról szóló 2011/65/EU (2011. június 8.) irányelve (RoHS irányelv) vonatkozó rendelkezéseit; valamint az Európai Parlament és a Tanács a gépekről és a 95/16/EK irányelv módosításáról szóló 2006/42/EK (2006. május 17.) irányelve vonatkozó rendelkezéseit a tagállamok jogrendjébe átültető rendelkezéseknek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében, a RoHS irányelv VI. mellékletében és a gépekről szóló irányelv II. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.

EN	**We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.** **This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.**
IT	Noi, i sottoscritti, con la presente dichiariamo che il(i) dispositivo(i) medico-diagnostico(i) *in vitro* sopra descritto(i) è(sono) conforme(i) alle disposizioni applicabili del regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medico-diagnostici *in vitro*; è(sono) inoltre conforme(i) alle disposizioni applicabili della direttiva 2011/65/UE del Parlamento europeo e del Consiglio dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche, e alle disposizioni applicabili della direttiva 2006/42/CE del Parlamento europeo e del Consiglio del 17 maggio 2006 relativa alle macchine e che modifica la direttiva 95/16/CE come recepite nelle legislazioni degli Stati membri. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD, all'allegato VI della direttiva ROHS e all'allegato II della direttiva macchine ed è rilasciata sotto la responsabilità esclusiva del fabbricante.
LV	Mēs, apakšā parakstījušies, ar šo paziņojam, ka iepriekš aprakstītā(-s) *in vitro* diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par *in vitro* diagnostikas medicīniskām ierīcēm un papildus prasībām, kas noteiktas Eiropas Parlamenta un Padomes Direktīvā 2011/65/ES (2011. gada 8. jūnijs) par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās un Eiropas Parlamenta un Padomes Direktīvā 2006/42/EK (2006. gada 17. maijs) par mašīnām, un ar kuru groza Direktīvu 95/16/EK, kā tā ieviesta dalībvalstu tiesību aktos. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu, ROHS direktīvas VI pielikumu un Direktīvas par mašīnām II pielikumu un par izdošanu atbild vienīgi ražotājs.
LT	Mes, toliau pasirašiusieji (-iusiosios), pareiškiame, kad anksčiau minėta (-os) *in vitro* diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl *in vitro* diagnostikos medicinos priemonių taikytinas nuostatas; taip pat ji (jos) atitinka 2011 m. birželio 8 d. Europos Parlamento ir Tarybos direktyvos 2011/65/ES dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo taikomas nuostatas ir 2006 m. gegužės 17 d. Europos Parlamento ir Tarybos direktyvos 2006/42/EB dėl mašinų, iš dalies keičiančios Direktyvą 95/16/EB, taikomas nuostatas, perkeltas į valstybių narių teisės aktus. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu, ROHS direktyvos VI priedu ir Mašinų direktyvos II priedu ir yra išduodama tik gamintojo atsakomybe.
NO	Vi, undertegnede, erklærer herved at utstyret til *in vitro*-diagnostikk som er anført ovenfor, er i samsvar med gjeldende bestemmelser i Europaparlaments- og rådsforordning (EU) 2017/746 av 5. april 2017 om medisinsk utstyr til *in vitro*-diagnostikk, og ytterligere overholder gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2011/65/EU av 8. juni 2011 om bruksbegrensninger av visse farlige stoffer i elektrisk og elektronisk utstyr, og til gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2006/42/EF av 17. mai 2006 om maskiner, og endring av direktiv 95/16/EF som innarbeidet i medlemsstatenes lovgivning. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen, vedlegg VI i ROHS-direktivet og vedlegg II i maskindirektivet og er utstedt under produsentens eneansvar.
PL	My, niżej podpisani, niniejszym oświadczamy, że wymieniony(-e) powyżej wyrób(wyroby) medyczny(-e) do diagnostyki in vitro spełnia(-ją) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki in vitro, a ponadto wymagania Dyrektywy 2011/65/UE Parlamentu Europejskiego i Rady z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym, Dyrektywy 2006/42/WE Parlamentu Europejskiego i Rady z dnia 17 maja 2006 r. w sprawie maszyn, zmieniającej Dyrektywę 95/16/WE, w sposób, w jaki zostały one wdrożone do ustawodawstwa państw członkowskich. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR, Załącznikiem VI Dyrektywy ROHS oraz Załącznikiem II Dyrektywy Maszynowej i wydana na wyłączną odpowiedzialność producenta.
PT	Nós, abaixo assinados, declaramos que os dispositivos médicos para diagnóstico *in vitro* descritos acima estão em conformidade com as disposições aplicáveis do Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho, de 5 de abril de 2017, relativo aos dispositivos médicos para diagnóstico *in vitro*; e adicionalmente, em conformidade com as disposições aplicáveis da Diretiva 2011/65/UE do Parlamento Europeu e do Conselho, de 8 de junho de 2011, relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrónicos, e com as disposições aplicáveis da Diretiva 2006/42/CE do Parlamento Europeu e do Conselho, de 17 de maio de 2006, sobre máquinas e que altera a Diretiva 95/16/CE, conforme transposta nas leis dos Estados membros. Esta declaração é feita de acordo com o Anexo IV do Regulamento IVD, o Anexo VI da Diretiva ROHS e o Anexo II da Diretiva relativa às Máquinas e é emitida sob a exclusiva responsabilidade do fabricante.
RO	Subsemnații, declarăm că dispozitivul (dispozitivele) medical(e) pentru diagnostic in vitro descrise mai sus sunt conforme cu dispozițiile aplicabile din Regulamentul (UE) 2017/746 al Parlamentului European și al Consiliului din 5 aprilie 2017 privind Dispozitivele medicale pentru diagnosticul in vitro; și, în plus, respectă dispozițiile aplicabile din Directiva 2011/65/UE a Parlamentului European și a Consiliului din 8 iunie 2011 privind restricția utilizării anumitor substanțe periculoase în echipamentele electrice și electronice și cu dispozițiile aplicabile din Directiva 2006/42/CE a Parlamentului European și a Consiliului din 17 mai 2006 privind utilajele și modificarea Directivei 95/16/CE, transpusă în legile statelor membre. Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD, anexa VI la Directiva ROHS și anexa II la Directiva utilajelor și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpísaní, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) in vitro uvedená(-é) vyššie je (sú) v zhode s príslušnými ustanoveniami Nariadenia Európskeho parlamentu a Rady (EÚ) 2017/746 z 5. apríla 2017 o diagnostických zdravotnických pomôckach in vitro; a že je (sú) ďalej v zhode s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2011/65/EÚ z 8. júna 2011 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach a s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2006/42/ES zo 17. mája 2006 o strojových zariadeniach a o zmene a doplnení Smernice 95/16/ES tak, ako boli transponované do zákonov členských štátov. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD, Prílohou VI k Smernici ROHS a Prílohou II k Smernici o strojových zariadeniach a vydáva sa na výhradnú zodpovednosť výrobcu.
SV	Vi, undertecknade, försäkrar härmed att den eller de medicintekniska produkter för *in vitro*-diagnostik som beskrivs ovan överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets förordning (EU) 2017/746 av den 5 april 2017 om medicintekniska produkter för *in vitro*-diagnostik samt även överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning samt med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2006/42/EG av den 17 maj 2006 om maskiner och om ändring av direktiv 95/16/EG (omarbetning) som införlivats i medlemsstaternas lagstiftning. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen, bilaga VI till ROHS-direktivet samt bilaga II till maskindirektivet och utfärdas under tillverkarens enskilda ansvar.
TR	Biz, aşağıda imzaları bulunan, yukarıda belirtilen in vitro diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli İn Vitro Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu ve ayrıca elektrikli ve elektronik cihazlarda belirli tehlikeli maddelerin kullanımının sınırlandırılmasına ilişkin 8 Haziran 2011 tarihli Konseyin ve 2011/65/EU sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine, makinelere ilişkin 17 Mayıs 2006 tarihli Konseyin ve 2006/42/EC sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine ve üye devlet yasalarına aktarılan 95/16/EC sayılı ek Direktife uygun olduğunu beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV, ROHS Direktifi Ek VI ve Makineler Direktifi Ek II uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altında yayınlanmıştır.

End of form

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0004FU
Basic UDI-DI Name: Water Bath Additive
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
9D29-20	Water Bath Additive	56676	W0201010185

Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 USA
Manufacturer SRN	US-MF-000017777
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue Charlottetown, Prince Edward Island CANADA C1E 2B9
Conformity Assessment Procedure	**Annex II and III**

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

Full Name:	Thomas Creel	Full Name:	Michele Smith-Waheed
Function:	Sr. Director, Instrument and Automation Quality	Function:	Associate Director, Regulatory Affairs
Signature:	Thomas Creel	Signature:	MSWaheed
Date of Approval:	20-May-2022	Date of Approval:	20-MAY-2022
Signed for, and on behalf of:	Abbott Laboratories, 1915 Hurd Drive, Irving, TX 75038		
Date Issued:	20-May-2022	Place Issued:	Irving, Texas
Supersedes:	N/A	Effective (Date or Lot Number):	20-May-2022

EN	EU Declaration of Conformity	Basic UDI-DI	Basic UDI-DI Name
BG	ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ	Базов UDI-DI	Наименование на базов UDI-DI
CS	EU PROHLÁŠENÍ O SHODĚ	Základní UDI-DI	Název základního UDI-DI
DA	EU-OVERENSSTEMMELSESERKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄTSERKLÄRUNG	Basis-UDI-DI	Basis-UDI-DI Name
EL	ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ	Βασικό UDI-DI	Ονομασία βασικού UDI-DI
ES	DECLARACIÓN UE DE CONFORMIDAD	UDI-DI Básico	Nombre UDI-DI Básico
ET	ELi vastavusdeklaratsioon	Põhi-UDI-DI	Põhi-UDI-DI nimi
FR	Déclaration de conformité UE	IUD-ID de base	Nom IUD-ID de base
HR	EU IZJAVA O SUKLADNOSTI	Osnovni UDI-DI	Naziv osnovnog UDI-DI
HU	EU-MEGFELELŐSÉGI NYILATKOZAT	Alapvető UDI-DI	Alapvető UDI-DI neve
IT	Dichiarazione di conformità UE	UDI-DI di base	Nome UDI-DI di base
LV	ES atbilstības deklarācija	Pamata UDI-DI	Pamata UDI-DI nosaukums
LT	ES ATITIKTIES DEKLARACIJA	Bazinis UDI-DI	Bazinio UDI-DI pavadinimas
NO	EU-samsvarserklæring	Grunnleggende UDI-DI	Grunnleggende UDI-DI-navn
PL	DEKLARACJA ZGODNOŚCI UE	Kod Basic UDI-DI	Nazwa kodu Basic UDI-DI
PT	DECLARAÇÃO UE DE CONFORMIDADE	UDI-DI básico	Nome UDI-DI Básico
RO	Declarația de Conformitate UE	UDI-DI de bază	Nume UDI-DI de bază
SK	EÚ VYHLÁSENIE O ZHODE	Základný UDI-DI	Názov základného UDI-DI
SV	EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE	Grundläggande UDI-DI	Namn på grundläggande UDI-DI
TR	AB Uygunluk Beyanı	Temel UDI-DI	Temel UDI-DI İsmi

EN	Risk Class	List Number and Size Code	Product and Trade Name
BG	Клас според риска	Каталожен номер и код на размера	Име на продукта и търговско наименование
CS	Riziková třída	Katalogové číslo a koncové dvojčíslí určující velikost soupravy	Název produktu a obchodní název
DA	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og varemærkenavn
DE	Risikoklasse	Bestellnummer und Größencode	Produkt- und Handelsname
EL	Κατηγορία κινδύνου	Κωδικός Προϊόντος και Κωδικός Συσκευασίας	Προϊόν και Εμπορική Ονομασία
ES	Clase de riesgo	Número de referencia y código de tamaño	Producto y marca comercial
ET	Riskiklass	Katalooginumber ja suurusekood	Toote nimetus ja kaubanimi
FR	Classe de risque	Référence	Nom de produit et de marque
HR	Klasa rizika	Kataloški broj i oznaka pakiranja	Naziv proizvoda i zaštićeni naziv
HU	Kockázati osztály	Listaszám és készletkiszerelés-kód	Termék- és kereskedelmi név
IT	Classe di rischio	Numero di listino e codice formato	Prodotto e nome commerciale
LV	Riska klase	Kataloga numurs un izmēra kods	Produkta nosaukums un tirdzniecības nosaukums
LT	Rizikos klasė	Katalogo numeris ir dydžio kodas	Gaminio ir prekybinis pavadinimai
NO	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og handelsnavn
PL	Klasa ryzyka	Numer katalogowy	Nazwa produktu i nazwa handlowa
PT	Classe de risco	Número de lista e código de apresentação	Produto e nome comercial
RO	Clasă de risc	Număr de listă și cod dimensiune	Denumirea produsului și denumirea comercială
SK	Riziková trieda	Katalógové číslo	Názov produktu a obchodný názov
SV	Riskklass	Listnummer och storlekskod	Produkt och firmanamn
TR	Risk Sınıfı	Liste Numarası ve Boyut Kodu	Ürün ve Ticari İsmi

EN	GMDN Code	EMDN Code	Manufacturer (Name and Address)	Manufacturer SRN
BG	Код GMDN	Код EMDN	Производител (име и адрес)	ЕРН на производителя
CS	Kód GMDN	Kód EMDN	Výrobce (název a adresa)	Jediné registrační číslo výrobce
DA	GMDN-kode	EMDN-kode	Fabrikant (navn og adresse)	Fabrikants SRN
DE	GMDN-Code	EMDN-Code	Hersteller (Name und Adresse)	Hersteller-SRN
EL	Κωδικός GMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κωδικός EMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κατασκευαστής (Όνομα και Διεύθυνση)	SRN (Μοναδικός Αριθμός Μητρώου) Κατασκευαστή
ES	Código GMDN	Código EMDN	Fabricante (nombre y dirección)	SRN (número de registro único) del fabricante
ET	GMDN-kood	EMDN-kood	Tootja (nimi ja aadress)	Tootja unikaalne registreerimisnumber
FR	Code GMDN	Code EMDN	Fabricant (nom et adresse)	Numéro d'enregistrement unique du fabricant
HR	GMDN kod	EMDN kod	Proizvođač (naziv i adresa)	SRN (jedinstveni registracijski broj) proizvođača
HU	GMDN-kód	EMDN-kód	Gyártó (név és cím)	Gyártó egyedi regisztrációs száma (SRN)
IT	Codice GMDN	Codice EMDN	Fabbricante (nome e indirizzo)	SRN (numero di registrazione unico) del fabbricante
LV	GMDN kods	EMDN kods	Ražotājs (nosaukums un adrese)	Ražotāja vienotais reģistrācijas numurs (VRN)
LT	Visuotinės medicinos priemonių nomenklatūros kodas	Europos medicinos priemonių nomenklatūros kodas	Gamintojas (pavadinimas ir adresas)	Gamintojo unikalusis registracijos numeris
NO	GMDN-kode	EMDN-kode	Produsent (navn og adresse)	Produsentens SRN
PL	Kod GMDN	Kod Europejskiej Nomenklatury Wyrobów Medycznych	Producent (nazwa i adres)	Niepowtarzalny numer rejestracyjny producenta
PT	Código GMDN	Código EMDN	Fabricante (Nome e Morada)	Número único de registo do fabricante
RO	Cod GMDN	Cod EMDN	Producător (nume şi adresă)	SRN producător
SK	Kód GMDN	Kód EMDN	Výrobca (Názov a adresa)	Jediné registračné číslo (SRN) výrobcu
SV	GMDN-kod	EMDN-kod	Tillverkare (namn och adress)	Tillverkarens SRN
TR	GMDN Kodu	EMDN Kodu	Üretici (İsim ve Adres)	Üretici SRN'si

EN	Authorized Representative (Name and Address)	Authorized Representative SRN	Produced by (Site of Manufacture) (Name and Address)
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)
CS	Zplnomocněný zástupce (název a adresa)	Jediné registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fabrikationssted) (Navn og adresse)
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Ονομασία και Διεύθυνση)
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootnud (tootmiskoht) (nimi ja aadress)
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)
LT	Įgaliotasis atstovas (pavadinimas ir adresas)	Įgaliotojo atstovo unikalusis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)
RO	Reprezentant autorizat (nume şi adresă)	SRN reprezentant autorizat	Produs de către (locaţie producţie) (nume şi adresă)
SK	Autorizovaný zástupca (názov a adresa)	Jediné registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)

EN	Conformity Assessment Procedure	Annex II and III	Full Name
BG	Процедура за оценка на съответствието	Приложение II и III	Пълно наименование
CS	Postup posuzování shody	Příloha II a III	Celý název
DA	Overensstemmelsesvurderingsprocedure	Bilag II og III	Fulde navn
DE	Konformitätsbewertungsverfahren	Anhang II und III	Vollständiger Name
EL	Διαδικασία αξιολόγησης συμμόρφωσης	Παράρτημα II και III	Πλήρης ονομασία
ES	Procedimiento de evaluación de la conformidad	Anexos II y III	Nombre completo
ET	Vastavushindamismenetlus	II ja III lisa	Täisnimi
FR	Procédure d'évaluation de la conformité	Annexes II et III	Nom complet
HR	Postupak ocjenjivanja sukladnosti	Prilog II. i III.	Puni naziv
HU	Megfelelőségértékelési eljárás	II. és III. melléklet	Teljes név
IT	Procedura di valutazione della conformità	Allegati II e III	Nome completo
LV	Atbilstības novērtēšanas procedūra	II un III pielikums	Pilns nosaukums
LT	Atitikties vertinimo procedūra	II ir III priedai	Vardas ir pavardė
NO	Framgangsmåte for samsvarsvurdering	Vedlegg II og III	Fullt navn
PL	Procedura oceny zgodności	Załącznik II oraz III	Imię i nazwisko
PT	Procedimento de avaliação da conformidade	Anexo II e III	Nome completo
RO	Procedură de evaluare a conformității	Anexa II și III	Numele complet
SK	Postup posudzovania zhody	Príloha II a III	Celý názov
SV	Förfarande för bedömning av överensstämmelse	Bilaga II och III	Fullständigt namn
TR	Uygunluk Değerlendirme Prosedürü	Ek II ve III	Adı Soyadı

EN	Function	Signed for, and on behalf of	Date Issued
BG	Длъжност	Подписано за и от името на	Дата на издаване
CS	Funkce	Podepsáno za a jménem	Datum vydání
DA	Funktion	Underskrevet for og på vegne af	Udstedelsesdato
DE	Funktion	Unterzeichnet für und im Auftrag von	Datum
EL	Λειτουργία	Υπογράφεται για και εκ μέρους του/της	Ημερομηνία έκδοσης
ES	Función	Firmada por, y en nombre de	Fecha
ET	Funktsioon	Alla kirjutanud (kelle poolt ja nimel)	Väljaandmise kuupäev
FR	Fonction	Signé par et au nom de	Date d'établissement
HR	Funkcija	Potpisano za i u ime	Datum izdavanja
HU	Beosztás	Aláíró a következő képviseletében és nevében	Kiadás dátuma
IT	Funzione	Firmato a nome e per conto di	Data di rilascio
LV	Amats	Parakstīts šādas personas vārdā	Izdošanas datums
LT	Pareigos	Subjekto, kurio vardu pasirašoma, pavadinimas	Išdavimo data
NO	Funksjon	Signert for, og på vegne av	Utstedelsesdato
PL	Funkcja	Podpisano w imieniu	Data wydania
PT	Função	Assinado e em nome de	Data de emissão
RO	Funcția	Semnat pentru și în numele	Data eliberării
SK	Funkcia	Podpísané za a v mene	Dátum vydania
SV	Funktion	Undertecknat för och på uppdrag av	Datum för utfärdande
TR	Görevi	Namına ve temsilen imza	Düzenlenme Tarihi

EN	Supersedes	Signature	Date of Approval
BG	Замества	Подпис	Дата на одобрение
CS	Nahrazuje	Podpis	Datum schválení
DA	Erstatter	Underskrift	Godkendelsesdato
DE	Ersetzt	Unterschrift	Datum der Genehmigung
EL	Αντικαθιστά	Υπογραφή	Ημερομηνία έγκρισης
ES	Sustituye	Firma	Fecha de aprobación
ET	Asendab	Allkiri	Heakskiitmise kuupäev
FR	Annule et remplace	Signature	Date de l'autorisation
HR	Zamjenjuje	Potpis	Datum odobrenja
HU	Hatálytalanítja a következő dokumentumot:	Aláírás	Jóváhagyás dátuma
IT	Sostituisce	Firma	Data di approvazione
LV	Aizstāj	Paraksts	Apstiprināšanas datums
LT	Pakeičia	Parašas	Patvirtinimo data
NO	Erstatter	Signatur	Godkjenningsdato
PL	Zastępuje	Podpis	Data zatwierdzenia
PT	Substitui	Assinatura	Data de aprovação
RO	Înlocuitor	Semnătură	Data aprobării
SK	Nahrádza	Podpis	Dátum schválenia
SV	Ersätter	Namnteckning	Datum för godkännande
TR	Yerini aldığı belge	İmza	Onay Tarihi

EN	Place Issued	Effective (Date or Lot Number)
BG	Място на издаване	В сила от/за (дата или номер на партида)
CS	Místo vydání	Účinné od (datum nebo číslo šarže)
DA	Udstedelsessted	Ikrafttrædelse (dato eller lotnummer)
DE	Ort	Gültig ab (Datum oder Chargenbezeichnung)
EL	Τόπος έκδοσης	Σε ισχύ από (Ημερομηνία ή αρ. παρτίδας)
ES	Expedida en	Efectiva (fecha o número de lote)
ET	Väljaandmise koht	Jõustumine (kuupäev või partiinumber)
FR	Lieu d'établissement	Entrée en vigueur (date ou numéro de lot)
HR	Mjesto izdavanja	Stupa na snagu (datum ili broj serije)
HU	Kiadás helye	Hatálybalépés (dátum vagy tételszám)
IT	Luogo di rilascio	Valido da (data o numero di lotto)
LV	Izdošanas vieta	Spēkā no (datums vai partijas numurs)
LT	Išdavimo vieta	Įsigalioja (data arba partijos numeris)
NO	Utstedelsessted	Gjelder fra (dato eller lotnummer)
PL	Miejsce wydania	Obowiązuje od (data lub numer partii)
PT	Local de emissão	Efetividade (Data ou número de lote)
RO	Locul eliberării	Valabilitate (data sau numărul lotului)
SK	Miesto vydania	Účinnosť od (dátum alebo číslo šarže)
SV	Plats för utfärdande	Verkställigt (datum eller lotnummer)
TR	Düzenlendiği Yer	Yürürlük (Tarih veya Lot Numarası)

EN	**We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.** **This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.**
BG	Ние, долуподписаните, с настоящото декларираме, че гореописаното(ите) медицинско(и) изделие(я) за инвитро диагностика отговаря(т) на приложимите разпоредби на Регламент (ЕС) 2017/746 на Европейския парламент и на Съвета от 5 април 2017 г. относно медицинските изделия за инвитро диагностика; освен това отговаря(т) на приложимите разпоредби на Директива 2011/65/ЕС на Европейския парламент и на Съвета от 8 юни 2011 г. относно ограничението на употребата на определени опасни вещества в електрическото и електронното оборудване и на приложимите разпоредби на Директива 2006/42/ЕО на Европейския парламент и на Съвета от 17 май 2006 г. относно машините, и за изменение на Директива 95/16/ЕО, както е транспонирана в националното законодателство на държавите членки. Тази декларация се прави в съответствие с Приложение IV на Регламента за IVD, Приложение VI на Директивата за ограничаване на опасните вещества (ROHS) и Приложение II на Директивата относно машините и за нейното издаване отговорност носи единствено производителят.
CS	My, níže podepsaní, tímto prohlašujeme, že diagnostický(-é) zdravotnický(-é) prostředek (prostředky) in vitro uvedený(-é) výše je (jsou) ve shodě s příslušnými ustanoveními nařízení Evropského parlamentu a Rady (EU) 2017/746 ze dne 5. dubna 2017 o diagnostických zdravotnických prostředcích in vitro; a že je (jsou) dále ve shodě s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2011/65/EU ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních a s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2006/42/ES ze dne 17. května 2006 o strojních zařízeních a o změně směrnice 95/16/ES, jak byla provedena ve vnitrostátním právu členských států. Toto prohlášení je v souladu s Přílohou IV nařízení IVD, Přílohou VI směrnice ROHS a Přílohou II směrnice o strojních zařízeních a je vydáno na výhradní odpovědnost výrobce.
DA	Vi, undertegnede, erklærer herved, at det in vitro-diagnostiske medicinske udstyr, der er beskrevet ovenfor, er i overensstemmelse med de gældende bestemmelser i Europa-Parlamentets og Rådets forordning (EU) 2017/746 af 5. april 2017 om in vitro-diagnostisk medicinsk udstyr, ligesom det overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2011/65/EU af 8. juni 2011 om begrænsning af brugen af visse farlige stoffer i elektrisk og elektronisk udstyr samt overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2006/42/EF af 17. maj 2006 om maskiner og ændring af direktiv 95/16/EF, som det er transponeret i medlemsstaternes lovgivning. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV, ROHS-direktivets bilag VI samt maskindirektivets bilag II og udstedes under fabrikantens eneansvar.
DE	Wir, die Unterzeichner, erklären hiermit, dass das oben beschriebene In-vitro-Diagnostikum/die oben beschriebenen In-vitro-Diagnostika die entsprechenden Bestimmungen der Verordnung (EU) 2017/746 des Europäischen Parlaments und des Rates vom 5. April 2017 über In-vitro-Diagnostika erfüllen und zusätzlich die entsprechenden Bestimmungen der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten sowie der Richtlinie 2006/42/EG des Europäischen Parlaments und des Rates vom 17. Mai 2006 über Maschinen und zur Änderung der Richtlinie 95/16/EG gemäß Umsetzung in den Gesetzen der Mitgliedsstaaten. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung, Anhang VI der RoHS-Richtlinie und Anhang II der Maschinen-Richtlinie und wird unter alleiniger Verantwortung des Herstellers ausgestellt.
EL	Εμείς, οι υπογράφοντες, δηλώνουμε με το παρόν ότι τα προαναφερόμενα διαγνωστικά ιατροτεχνολογικά προϊόντα συμμορφώνονται με τις ισχύουσες διατάξεις του Κανονισμού (ΕΕ) 2017/746 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 5ης Απριλίου 2017 σχετικά με τα in vitro διαγνωστικά ιατροτεχνολογικά προϊόντα και επίσης συμμορφώνονται με τις ισχύουσες διατάξεις της Οδηγίας 2011/65/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 8ης Ιουνίου 2011 σχετικά με τους περιορισμούς στη χρήση συγκεκριμένων επικίνδυνων ουσιών στον ηλεκτρικό και ηλεκτρονικό εξοπλισμό, καθώς και με τις ισχύουσες διατάξεις της Οδηγίας 2006/42/ΕΚ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 17ης Μαΐου 2006 σχετικά με τον μηχανικό εξοπλισμό και την τροποποιητική Οδηγία 95/16/ΕΚ όπως αυτή μεταφέρθηκε στη νομοθεσία των κρατών μελών. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD, το Παράρτημα VI της Οδηγίας ROHS και το Παράρτημα II της Οδηγίας για τον μηχανικό εξοπλισμό και εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή.
ES	Nosotros, los abajo firmantes, por la presente declaramos que el(los) producto(s) sanitario(s) para diagnóstico *in vitro* descrito(s) anteriormente cumple(n) las disposiciones aplicables del reglamento (UE) 2017/746 del Parlamento Europeo y del Consejo del 5 de abril de 2017 sobre productos sanitarios para diagnóstico *in vitro*; y además cumple(n) las disposiciones aplicables de la Directiva 2011/65/EU del Parlamento Europeo y del Consejo del 8 de junio de 2011 sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos, y las disposiciones aplicables de la Directiva 2006/42/EC del Parlamento Europeo y del Consejo del 17 de mayo de 2006 sobre maquinaria, y la Directiva de enmienda 95/16/EC tal y como se ha incorporado en las leyes de los Estados Miembros. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD, Anexo VI de la Directiva ROHS y Anexo II de la Directiva de máquinas y es emitida bajo la exclusiva responsabilidad del fabricante.
ET	Meie, allakirjutanud, kinnitame, et eespool kirjeldatud *in vitro* diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (*in vitro* diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele ning lisaks vastab see kohaldatavatele sätetele Euroopa Parlamendi ja nõukogu 8. juuni 2011. aasta direktiivis 2011/65/EL (teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes) ja Euroopa Parlamendi ja nõukogu direktiivis 2006/42/EÜ, 17. mai 2006, mis käsitleb masinaid ja millega muudetakse direktiivi 95/16/EÜ, nagu see on üle võetud liikmesriikide seadustesse. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale, ROHS direktiivi VI lisale ja masinadirektiivi II lisale ning see on välja antud tootja vastutusel.
FR	Nous soussigné(e)s, déclarons par la présente que le(s) dispositif(s) médical(aux) de diagnostic *in vitro* indiqué(s) ci-dessus est/sont conforme(s) aux dispositions applicables du Règlement (UE) 2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic *in vitro*, aux dispositions applicables de la Directive 2011/65/UE du Parlement européen et du Conseil du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques, aux dispositions applicables de la Directive 2006/42/CE du Parlement européen et du Conseil du 17 mai 2006 relative aux machines et modifiant la Directive 95/16/CE, telles que transposées dans le droit national des États membres. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV, à l'Annexe VI de la Directive ROHS ainsi qu'à l'Annexe II de la Directive Machines sous la seule responsabilité du fabricant.
HR	Mi, niže potpisani, ovim putem izjavljujemo da su gore navedeni *in vitro* dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o *in vitro* dijagnostičkim medicinskim proizvodima; i dodatno primjenjivim odredbama Direktive 2011/65/EU Europskog parlamenta i Vijeća od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi, te primjenjivim odredbama Direktive 2006/42/EZ Europskog parlamenta i Vijeća od 17. svibnja 2006. o strojevima zamjenjujući Direktivu 95/16/EZ kako je pretočeno u zakone država članica. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD, Prilogom VI. Direktive ROHS i Prilogom II. Direktive o strojevima i izdaje se pod isključivom odgovornošću proizvođača.
HU	Alulírottak ezennel kijelentjük, hogy a fent leírt in vitro orvostechnikai eszköz(ök) megfelel(nek) az Európai Parlament és a Tanács in vitro diagnosztikai orvostechnikai eszközökről szóló (EU) 2017/746 (2017. április 5.) rendelete vonatkozó rendelkezéseit; továbbá az Európai Parlament és a Tanács egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról szóló 2011/65/EU (2011. június 8.) irányelve (RoHS irányelv) vonatkozó rendelkezéseit; valamint az Európai Parlament és a Tanács a gépekről és a 95/16/EK irányelv módosításáról szóló 2006/42/EK (2006. május 17.) irányelve vonatkozó rendelkezéseit a tagállamok jogrendjébe átültető rendelkezéseknek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében, a RoHS irányelv VI. mellékletében és a gépekről szóló irányelv II. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.

EN	**We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.** **This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.**
IT	Noi, i sottoscritti, con la presente dichiariamo che il(i) dispositivo(i) medico-diagnostico(i) *in vitro* sopra descritto(i) è(sono) conforme(i) alle disposizioni applicabili del regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medico-diagnostici *in vitro*; è(sono) inoltre conforme(i) alle disposizioni applicabili della direttiva 2011/65/UE del Parlamento europeo e del Consiglio dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche, e alle disposizioni applicabili della direttiva 2006/42/CE del Parlamento europeo e del Consiglio del 17 maggio 2006 relativa alle macchine e che modifica la direttiva 95/16/CE come recepite nelle legislazioni degli Stati membri. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD, all'allegato VI della direttiva ROHS e all'allegato II della direttiva macchine ed è rilasciata sotto la responsabilità esclusiva del fabbricante.
LV	Mēs, apakšā parakstījušies, ar šo paziņojam, ka iepriekš aprakstītā(-s) *in vitro* diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par *in vitro* diagnostikas medicīniskām ierīcēm un papildus prasībām, kas noteiktas Eiropas Parlamenta un Padomes Direktīvā 2011/65/ES (2011. gada 8. jūnijs) par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās un Eiropas Parlamenta un Padomes Direktīvā 2006/42/EK (2006. gada 17. maijs) par mašīnām, un ar kuru groza Direktīvu 95/16/EK, kā tā ieviesta dalībvalstu tiesību aktos. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu, ROHS direktīvas VI pielikumu un Direktīvas par mašīnām II pielikumu un par izdošanu atbild vienīgi ražotājs.
LT	Mes, toliau pasirašiusieji (-iusiosios), pareiškiame, kad anksčiau minėta (-os) *in vitro* diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl *in vitro* diagnostikos medicinos priemonių taikytinas nuostatas; taip pat ji (jos) atitinka 2011 m. birželio 8 d. Europos Parlamento ir Tarybos direktyvos 2011/65/ES dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo taikomas nuostatas ir 2006 m. gegužės 17 d. Europos Parlamento ir Tarybos direktyvos 2006/42/EB dėl mašinų, iš dalies keičiančios Direktyvą 95/16/EB, taikomas nuostatas, perkeltas į valstybių narių teisės aktus. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu, ROHS direktyvos VI priedu ir Mašinų direktyvos II priedu ir yra išduodama tik gamintojo atsakomybe.
NO	Vi, undertegnede, erklærer herved at utstyret til *in vitro*-diagnostikk som er anført ovenfor, er i samsvar med gjeldende bestemmelser i Europaparlaments- og rådsforordning (EU) 2017/746 av 5. april 2017 om medisinsk utstyr til *in vitro*-diagnostikk, og ytterligere overholder gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2011/65/EU av 8. juni 2011 om bruksbegrensninger av visse farlige stoffer i elektrisk og elektronisk utstyr, og til gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2006/42/EF av 17. mai 2006 om maskiner, og endring av direktiv 95/16/EF som innarbeidet i medlemsstatenes lovgivning. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen, vedlegg VI i ROHS-direktivet og vedlegg II i maskindirektivet og er utstedt under produsentens eneansvar.
PL	My, niżej podpisani, niniejszym oświadczamy, że wymieniony(-e) powyżej wyrób(wyroby) medyczny(-e) do diagnostyki in vitro spełnia(-ją) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki in vitro, a ponadto wymagania Dyrektywy 2011/65/UE Parlamentu Europejskiego i Rady z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym, Dyrektywy 2006/42/WE Parlamentu Europejskiego i Rady z dnia 17 maja 2006 r. w sprawie maszyn, zmieniającej Dyrektywę 95/16/WE, w sposób, w jaki zostały one wdrożone do ustawodawstwa państw członkowskich. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR, Załącznikiem VI Dyrektywy ROHS oraz Załącznikiem II Dyrektywy Maszynowej i wydana na wyłączną odpowiedzialność producenta.
PT	Nós, abaixo assinados, declaramos que os dispositivos médicos para diagnóstico *in vitro* descritos acima estão em conformidade com as disposições aplicáveis do Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho, de 5 de abril de 2017, relativo aos dispositivos médicos para diagnóstico *in vitro*; e adicionalmente, em conformidade com as disposições aplicáveis da Diretiva 2011/65/UE do Parlamento Europeu e do Conselho, de 8 de junho de 2011, relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrónicos, e com as disposições aplicáveis da Diretiva 2006/42/CE do Parlamento Europeu e do Conselho, de 17 de maio de 2006, sobre máquinas e que altera a Diretiva 95/16/CE, conforme transposta nas leis dos Estados membros. Esta declaração é feita de acordo com o Anexo IV do Regulamento IVD, o Anexo VI da Diretiva ROHS e o Anexo II da Diretiva relativa às Máquinas e é emitida sob a exclusiva responsabilidade do fabricante.
RO	Subsemnații, declarăm că dispozitivul (dispozitivele) medical(e) pentru diagnostic in vitro descrise mai sus sunt conforme cu dispozițiile aplicabile din Regulamentul (UE) 2017/746 al Parlamentului European și al Consiliului din 5 aprilie 2017 privind Dispozitivele medicale pentru diagnosticul in vitro; și, în plus, respectă dispozițiile aplicabile din Directiva 2011/65/UE a Parlamentului European și a Consiliului din 8 iunie 2011 privind restricția utilizării anumitor substanțe periculoase în echipamentele electrice și electronice și cu dispozițiile aplicabile din Directiva 2006/42/CE a Parlamentului European și a Consiliului din 17 mai 2006 privind utilajele și modificarea Directivei 95/16/CE, transpusă în legile statelor membre. Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD, anexa VI la Directiva ROHS și anexa II la Directiva utilajelor și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpísaní, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) in vitro uvedená(-é) vyššie je (sú) v zhode s príslušnými ustanoveniami Nariadenia Európskeho parlamentu a Rady (EÚ) 2017/746 z 5. apríla 2017 o diagnostických zdravotnických pomôckach in vitro; a že je (sú) ďalej v zhode s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2011/65/EÚ z 8. júna 2011 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach a s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2006/42/ES zo 17. mája 2006 o strojových zariadeniach a o zmene a doplnení Smernice 95/16/ES tak, ako boli transponované do zákonov členských štátov. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD, Prílohou VI k Smernici ROHS a Prílohou II k Smernici o strojových zariadeniach a vydáva sa na výhradnú zodpovednosť výrobcu.
SV	Vi, undertecknade, försäkrar härmed att den eller de medicintekniska produkter för *in vitro*-diagnostik som beskrivs ovan överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets förordning (EU) 2017/746 av den 5 april 2017 om medicintekniska produkter för *in vitro*-diagnostik samt även överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning samt med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2006/42/EG av den 17 maj 2006 om maskiner och om ändring av direktiv 95/16/EG (omarbetning) som införlivats i medlemsstaternas lagstiftning. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen, bilaga VI till ROHS-direktivet samt bilaga II till maskindirektivet och utfärdas under tillverkarens enskilda ansvar.
TR	Biz, aşağıda imzaları bulunan, yukarıda belirtilen in vitro diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli İn Vitro Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu ve ayrıca elektrikli ve elektronik cihazlarda belirli tehlikeli maddelerin kullanımının sınırlandırılmasına ilişkin 8 Haziran 2011 tarihli Konseyin ve 2011/65/EU sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine, makinelere ilişkin 17 Mayıs 2006 tarihli Konseyin ve 2006/42/EC sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine ve üye devlet yasalarına aktarılan 95/16/EC sayılı ek Direktife uygun olduğunu beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV, ROHS Direktifi Ek VI ve Makineler Direktifi Ek II uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altında yayınlanmıştır.

End of form

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0004FU
Basic UDI-DI Name: Acid Wash
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
6K01-20	Acid Wash	56676	W0201010185

Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 USA
Manufacturer SRN	US-MF-000017777
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	Fisher Diagnostics 8365 Valley Pike Middletown VA 22645 USA
Conformity Assessment Procedure	**Annex II and III**

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

Full Name: Thomas Creel
Function: Sr. Director, Instrument and Automation Quality
Signature: Thomas Creel
Date of Approval: 20-May-2022

Full Name: Michele Smith-Waheed
Function: Associate Director, Regulatory Affairs
Signature: MSWaheed
Date of Approval: 20-May-2022

Signed for, and on behalf of: Abbott Laboratories, 1915 Hurd Drive, Irving, TX 75038

Date Issued: 20-MAY-2022
Supersedes: N/A

Place Issued: Irving, Texas
Effective (Date or Lot Number): 20-MAY-2022

EN	EU Declaration of Conformity	Basic UDI-DI	Basic UDI-DI Name
BG	ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ	Базов UDI-DI	Наименование на базов UDI-DI
CS	EU PROHLÁŠENÍ O SHODĚ	Základní UDI-DI	Název základního UDI-DI
DA	EU-OVERENSSTEMMELSESERKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄTSERKLÄRUNG	Basis-UDI-DI	Basis-UDI-DI Name
EL	ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ	Βασικό UDI-DI	Ονομασία βασικού UDI-DI
ES	DECLARACIÓN UE DE CONFORMIDAD	UDI-DI Básico	Nombre UDI-DI Básico
ET	ELi vastavusdeklaratsioon	Põhi-UDI-DI	Põhi-UDI-DI nimi
FR	Déclaration de conformité UE	IUD-ID de base	Nom IUD-ID de base
HR	EU IZJAVA O SUKLADNOSTI	Osnovni UDI-DI	Naziv osnovnog UDI-DI
HU	EU-MEGFELELŐSÉGI NYILATKOZAT	Alapvető UDI-DI	Alapvető UDI-DI neve
IT	Dichiarazione di conformità UE	UDI-DI di base	Nome UDI-DI di base
LV	ES atbilstības deklarācija	Pamata UDI-DI	Pamata UDI-DI nosaukums
LT	ES ATITIKTIES DEKLARACIJA	Bazinis UDI-DI	Bazinio UDI-DI pavadinimas
NO	EU-samsvarserklæring	Grunnleggende UDI-DI	Grunnleggende UDI-DI-navn
PL	DEKLARACJA ZGODNOŚCI UE	Kod Basic UDI-DI	Nazwa kodu Basic UDI-DI
PT	DECLARAÇÃO UE DE CONFORMIDADE	UDI-DI básico	Nome UDI-DI Básico
RO	Declarația de Conformitate UE	UDI-DI de bază	Nume UDI-DI de bază
SK	EÚ VYHLÁSENIE O ZHODE	Základný UDI-DI	Názov základného UDI-DI
SV	EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE	Grundläggande UDI-DI	Namn på grundläggande UDI-DI
TR	AB Uygunluk Beyanı	Temel UDI-DI	Temel UDI-DI İsmi

EN	Risk Class	List Number and Size Code	Product and Trade Name
BG	Клас според риска	Каталожен номер и код на размера	Име на продукта и търговско наименование
CS	Riziková třída	Katalogové číslo a koncové dvojčíslí určující velikost soupravy	Název produktu a obchodní název
DA	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og varemærkenavn
DE	Risikoklasse	Bestellnummer und Größencode	Produkt- und Handelsname
EL	Κατηγορία κινδύνου	Κωδικός Προϊόντος και Κωδικός Συσκευασίας	Προϊόν και Εμπορική Ονομασία
ES	Clase de riesgo	Número de referencia y código de tamaño	Producto y marca comercial
ET	Riskiklass	Katalooginumber ja suurusekood	Toote nimetus ja kaubanimi
FR	Classe de risque	Référence	Nom de produit et de marque
HR	Klasa rizika	Kataloški broj i oznaka pakiranja	Naziv proizvoda i zaštićeni naziv
HU	Kockázati osztály	Listaszám és készletkiszerelés-kód	Termék- és kereskedelmi név
IT	Classe di rischio	Numero di listino e codice formato	Prodotto e nome commerciale
LV	Riska klase	Kataloga numurs un izmēra kods	Produkta nosaukums un tirdzniecības nosaukums
LT	Rizikos klasė	Katalogo numeris ir dydžio kodas	Gaminio ir prekybinis pavadinimai
NO	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og handelsnavn
PL	Klasa ryzyka	Numer katalogowy	Nazwa produktu i nazwa handlowa
PT	Classe de risco	Número de lista e código de apresentação	Produto e nome comercial
RO	Clasă de risc	Număr de listă și cod dimensiune	Denumirea produsului și denumirea comercială
SK	Riziková trieda	Katalógové číslo	Názov produktu a obchodný názov
SV	Riskklass	Listnummer och storlekskod	Produkt och firmanamn
TR	Risk Sınıfı	Liste Numarası ve Boyut Kodu	Ürün ve Ticari İsmi

EN	GMDN Code	EMDN Code	Manufacturer (Name and Address)	Manufacturer SRN
BG	Код GMDN	Код EMDN	Производител (име и адрес)	ЕРН на производителя
CS	Kód GMDN	Kód EMDN	Výrobce (název a adresa)	Jediné registrační číslo výrobce
DA	GMDN-kode	EMDN-kode	Fabrikant (navn og adresse)	Fabrikants SRN
DE	GMDN-Code	EMDN-Code	Hersteller (Name und Adresse)	Hersteller-SRN
EL	Κωδικός GMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κωδικός EMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κατασκευαστής (Όνομα και Διεύθυνση)	SRN (Μοναδικός Αριθμός Μητρώου) Κατασκευαστή
ES	Código GMDN	Código EMDN	Fabricante (nombre y dirección)	SRN (número de registro único) del fabricante
ET	GMDN-kood	EMDN-kood	Tootja (nimi ja aadress)	Tootja unikaalne registreerimisnumber
FR	Code GMDN	Code EMDN	Fabricant (nom et adresse)	Numéro d'enregistrement unique du fabricant
HR	GMDN kod	EMDN kod	Proizvođač (naziv i adresa)	SRN (jedinstveni registracijski broj) proizvođača
HU	GMDN-kód	EMDN-kód	Gyártó (név és cím)	Gyártó egyedi regisztrációs száma (SRN)
IT	Codice GMDN	Codice EMDN	Fabbricante (nome e indirizzo)	SRN (numero di registrazione unico) del fabbricante
LV	GMDN kods	EMDN kods	Ražotājs (nosaukums un adrese)	Ražotāja vienotais reģistrācijas numurs (VRN)
LT	Visuotinės medicinos priemonių nomenklatūros kodas	Europos medicinos priemonių nomenklatūros kodas	Gamintojas (pavadinimas ir adresas)	Gamintojo unikalusis registracijos numeris
NO	GMDN-kode	EMDN-kode	Produsent (navn og adresse)	Produsentens SRN
PL	Kod GMDN	Kod Europejskiej Nomenklatury Wyrobów Medycznych	Producent (nazwa i adres)	Niepowtarzalny numer rejestracyjny producenta
PT	Código GMDN	Código EMDN	Fabricante (Nome e Morada)	Número único de registo do fabricante
RO	Cod GMDN	Cod EMDN	Producător (nume și adresă)	SRN producător
SK	Kód GMDN	Kód EMDN	Výrobca (Názov a adresa)	Jediné registračné číslo (SRN) výrobcu
SV	GMDN-kod	EMDN-kod	Tillverkare (namn och adress)	Tillverkarens SRN
TR	GMDN Kodu	EMDN Kodu	Üretici (İsim ve Adres)	Üretici SRN'si

EN	Authorized Representative (Name and Address)	Authorized Representative SRN	Produced by (Site of Manufacture) (Name and Address)
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)
CS	Zplnomocněný zástupce (název a adresa)	Jediné registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fabrikationssted) (Navn og adresse)
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Ονομασία και Διεύθυνση)
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootnud (tootmiskoht) (nimi ja aadress)
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)
LT	Įgaliotasis atstovas (pavadinimas ir adresas)	Įgaliotojo atstovo unikalusis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)
RO	Reprezentant autorizat (nume și adresă)	SRN reprezentant autorizat	Produs de către (locație producție) (nume și adresă)
SK	Autorizovaný zástupca (názov a adresa)	Jediné registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)

EN	Conformity Assessment Procedure	Annex II and III	Full Name
BG	Процедура за оценка на съответствието	Приложение II и III	Пълно наименование
CS	Postup posuzování shody	Příloha II a III	Celý název
DA	Overensstemmelsesvurderingsprocedure	Bilag II og III	Fulde navn
DE	Konformitätsbewertungsverfahren	Anhang II und III	Vollständiger Name
EL	Διαδικασία αξιολόγησης συμμόρφωσης	Παράρτημα II και III	Πλήρης ονομασία
ES	Procedimiento de evaluación de la conformidad	Anexos II y III	Nombre completo
ET	Vastavushindamismenetlus	II ja III lisa	Täisnimi
FR	Procédure d'évaluation de la conformité	Annexes II et III	Nom complet
HR	Postupak ocjenjivanja sukladnosti	Prilog II. i III.	Puni naziv
HU	Megfelelőségértékelési eljárás	II. és III. melléklet	Teljes név
IT	Procedura di valutazione della conformità	Allegati II e III	Nome completo
LV	Atbilstības novērtēšanas procedūra	II un III pielikums	Pilns nosaukums
LT	Atitikties vertinimo procedūra	II ir III priedai	Vardas ir pavardė
NO	Framgangsmåte for samsvarsvurdering	Vedlegg II og III	Fullt navn
PL	Procedura oceny zgodności	Załącznik II oraz III	Imię i nazwisko
PT	Procedimento de avaliação da conformidade	Anexo II e III	Nome completo
RO	Procedură de evaluare a conformității	Anexa II și III	Numele complet
SK	Postup posudzovania zhody	Príloha II a III	Celý názov
SV	Förfarande för bedömning av överensstämmelse	Bilaga II och III	Fullständigt namn
TR	Uygunluk Değerlendirme Prosedürü	Ek II ve III	Adı Soyadı

EN	Function	Signed for, and on behalf of	Date Issued
BG	Длъжност	Подписано за и от името на	Дата на издаване
CS	Funkce	Podepsáno za a jménem	Datum vydání
DA	Funktion	Underskrevet for og på vegne af	Udstedelsesdato
DE	Funktion	Unterzeichnet für und im Auftrag von	Datum
EL	Λειτουργία	Υπογράφεται για και εκ μέρους του/της	Ημερομηνία έκδοσης
ES	Función	Firmada por, y en nombre de	Fecha
ET	Funktsioon	Alla kirjutanud (kelle poolt ja nimel)	Väljaandmise kuupäev
FR	Fonction	Signé par et au nom de	Date d'établissement
HR	Funkcija	Potpisano za i u ime	Datum izdavanja
HU	Beosztás	Aláíró a következő képviseletében és nevében	Kiadás dátuma
IT	Funzione	Firmato a nome e per conto di	Data di rilascio
LV	Amats	Parakstīts šādas personas vārdā	Izdošanas datums
LT	Pareigos	Subjekto, kurio vardu pasirašoma, pavadinimas	Išdavimo data
NO	Funksjon	Signert for, og på vegne av	Utstedelsesdato
PL	Funkcja	Podpisano w imieniu	Data wydania
PT	Função	Assinado e em nome de	Data de emissão
RO	Funcția	Semnat pentru și în numele	Data eliberării
SK	Funkcia	Podpísané za a v mene	Dátum vydania
SV	Funktion	Undertecknat för och på uppdrag av	Datum för utfärdande
TR	Görevi	Namına ve temsilen imza	Düzenlenme Tarihi

EN	Supersedes	Signature	Date of Approval
BG	Замества	Подпис	Дата на одобрение
CS	Nahrazuje	Podpis	Datum schválení
DA	Erstatter	Underskrift	Godkendelsesdato
DE	Ersetzt	Unterschrift	Datum der Genehmigung
EL	Αντικαθιστά	Υπογραφή	Ημερομηνία έγκρισης
ES	Sustituye	Firma	Fecha de aprobación
ET	Asendab	Allkiri	Heakskiitmise kuupäev
FR	Annule et remplace	Signature	Date de l'autorisation
HR	Zamjenjuje	Potpis	Datum odobrenja
HU	Hatálytalanítja a következő dokumentumot:	Aláírás	Jóváhagyás dátuma
IT	Sostituisce	Firma	Data di approvazione
LV	Aizstāj	Paraksts	Apstiprināšanas datums
LT	Pakeičia	Parašas	Patvirtinimo data
NO	Erstatter	Signatur	Godkjenningsdato
PL	Zastępuje	Podpis	Data zatwierdzenia
PT	Substitui	Assinatura	Data de aprovação
RO	Înlocuitor	Semnătură	Data aprobării
SK	Nahrádza	Podpis	Dátum schválenia
SV	Ersätter	Namnteckning	Datum för godkännande
TR	Yerini aldığı belge	İmza	Onay Tarihi

EN	Place Issued	Effective (Date or Lot Number)
BG	Място на издаване	В сила от/за (дата или номер на партида)
CS	Místo vydání	Účinné od (datum nebo číslo šarže)
DA	Udstedelsessted	Ikrafttrædelse (dato eller lotnummer)
DE	Ort	Gültig ab (Datum oder Chargenbezeichnung)
EL	Τόπος έκδοσης	Σε ισχύ από (Ημερομηνία ή αρ. παρτίδας)
ES	Expedida en	Efectiva (fecha o número de lote)
ET	Väljaandmise koht	Jõustumine (kuupäev või partiinumber)
FR	Lieu d'établissement	Entrée en vigueur (date ou numéro de lot)
HR	Mjesto izdavanja	Stupa na snagu (datum ili broj serije)
HU	Kiadás helye	Hatálybalépés (dátum vagy tételszám)
IT	Luogo di rilascio	Valido da (data o numero di lotto)
LV	Izdošanas vieta	Spēkā no (datums vai partijas numurs)
LT	Išdavimo vieta	Įsigalioja (data arba partijos numeris)
NO	Utstedelsessted	Gjelder fra (dato eller lotnummer)
PL	Miejsce wydania	Obowiązuje od (data lub numer partii)
PT	Local de emissão	Efetividade (Data ou número de lote)
RO	Locul eliberării	Valabilitate (data sau numărul lotului)
SK	Miesto vydania	Účinnosť od (dátum alebo číslo šarže)
SV	Plats för utfärdande	Verkställigt (datum eller lotnummer)
TR	Düzenlendiği Yer	Yürürlük (Tarih veya Lot Numarası)

EN	**We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.** **This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.**
BG	Ние, долуподписаните, с настоящото декларираме, че гореописаното(ите) медицинско(и) изделие(я) за инвитро диагностика отговаря(т) на приложимите разпоредби на Регламент (ЕС) 2017/746 на Европейския парламент и на Съвета от 5 април 2017 г. относно медицинските изделия за инвитро диагностика; освен това отговаря(т) на приложимите разпоредби на Директива 2011/65/ЕС на Европейския парламент и на Съвета от 8 юни 2011 г. относно ограничението на употребата на определени опасни вещества в електрическото и електронното оборудване и на приложимите разпоредби на Директива 2006/42/ЕО на Европейския парламент и на Съвета от 17 май 2006 г. относно машините, и за изменение на Директива 95/16/ЕО, както е транспонирана в националното законодателство на държавите членки. Тази декларация се прави в съответствие с Приложение IV на Регламента за IVD, Приложение VI на Директивата за ограничаване на опасните вещества (ROHS) и Приложение II на Директивата относно машините и за нейното издаване отговорност носи единствено производителят.
CS	My, níže podepsaní, tímto prohlašujeme, že diagnostický(-é) zdravotnický(-é) prostředek (prostředky) in vitro uvedený(-é) výše je (jsou) ve shodě s příslušnými ustanoveními nařízení Evropského parlamentu a Rady (EU) 2017/746 ze dne 5. dubna 2017 o diagnostických zdravotnických prostředcích in vitro; a že je (jsou) dále ve shodě s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2011/65/EU ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních a s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2006/42/ES ze dne 17. května 2006 o strojních zařízeních a o změně směrnice 95/16/ES, jak byla provedena ve vnitrostátním právu členských států. Toto prohlášení je v souladu s Přílohou IV nařízení IVD, Přílohou VI směrnice ROHS a Přílohou II směrnice o strojních zařízeních a je vydáno na výhradní odpovědnost výrobce.
DA	Vi, undertegnede, erklærer herved, at det in vitro-diagnostiske medicinske udstyr, der er beskrevet ovenfor, er i overensstemmelse med de gældende bestemmelser i Europa-Parlamentets og Rådets forordning (EU) 2017/746 af 5. april 2017 om in vitro-diagnostisk medicinsk udstyr, ligesom det overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2011/65/EU af 8. juni 2011 om begrænsning af brugen af visse farlige stoffer i elektrisk og elektronisk udstyr samt overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2006/42/EF af 17. maj 2006 om maskiner og ændring af direktiv 95/16/EF, som det er transponeret i medlemsstaternes lovgivning. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV, ROHS-direktivets bilag VI samt maskindirektivets bilag II og udstedes under fabrikantens eneansvar.
DE	Wir, die Unterzeichner, erklären hiermit, dass das oben beschriebene In-vitro-Diagnostikum/die oben beschriebenen In-vitro-Diagnostika die entsprechenden Bestimmungen der Verordnung (EU) 2017/746 des Europäischen Parlaments und des Rates vom 5. April 2017 über In-vitro-Diagnostika erfüllen und zusätzlich die entsprechenden Bestimmungen der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten sowie der Richtlinie 2006/42/EG des Europäischen Parlaments und des Rates vom 17. Mai 2006 über Maschinen und zur Änderung der Richtlinie 95/16/EG gemäß Umsetzung in den Gesetzen der Mitgliedsstaaten. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung, Anhang VI der RoHS-Richtlinie und Anhang II der Maschinen-Richtlinie und wird unter alleiniger Verantwortung des Herstellers ausgestellt.
EL	Εμείς, οι υπογράφοντες, δηλώνουμε με το παρόν ότι τα προαναφερόμενα διαγνωστικά ιατροτεχνολογικά προϊόντα συμμορφώνονται με τις ισχύουσες διατάξεις του Κανονισμού (ΕΕ) 2017/746 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 5ης Απριλίου 2017 σχετικά με τα in vitro διαγνωστικά ιατροτεχνολογικά προϊόντα και επίσης συμμορφώνονται με τις ισχύουσες διατάξεις της Οδηγίας 2011/65/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 8ης Ιουνίου 2011 σχετικά με τους περιορισμούς στη χρήση συγκεκριμένων επικίνδυνων ουσιών στον ηλεκτρικό και ηλεκτρονικό εξοπλισμό, καθώς και με τις ισχύουσες διατάξεις της Οδηγίας 2006/42/ΕΚ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 17ης Μαΐου 2006 σχετικά με τον μηχανικό εξοπλισμό και την τροποποιητική Οδηγία 95/16/ΕΚ όπως αυτή μεταφέρθηκε στη νομοθεσία των κρατών μελών. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD, το Παράρτημα VI της Οδηγίας ROHS και το Παράρτημα II της Οδηγίας για τον μηχανικό εξοπλισμό και εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή.
ES	Nosotros, los abajo firmantes, por la presente declaramos que el(los) producto(s) sanitario(s) para diagnóstico *in vitro* descrito(s) anteriormente cumple(n) las disposiciones aplicables del reglamento (UE) 2017/746 del Parlamento Europeo y del Consejo del 5 de abril de 2017 sobre productos sanitarios para diagnóstico *in vitro*; y además cumple(n) las disposiciones aplicables de la Directiva 2011/65/EU del Parlamento Europeo y del Consejo del 8 de junio de 2011 sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos, y las disposiciones aplicables de la Directiva 2006/42/EC del Parlamento Europeo y del Consejo del 17 de mayo de 2006 sobre maquinaria, y la Directiva de enmienda 95/16/EC tal y como se ha incorporado en las leyes de los Estados Miembros. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD, Anexo VI de la Directiva ROHS y Anexo II de la Directiva de máquinas y es emitida bajo la exclusiva responsabilidad del fabricante.
ET	Meie, allakirjutanud, kinnitame, et eespool kirjeldatud *in vitro* diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (*in vitro* diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele ning lisaks vastab see kohaldatavatele sätetele Euroopa Parlamendi ja nõukogu 8. juuni 2011. aasta direktiivis 2011/65/EL (teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes) ja Euroopa Parlamendi ja nõukogu direktiivis 2006/42/EÜ, 17. mai 2006, mis käsitleb masinaid ja millega muudetakse direktiivi 95/16/EÜ, nagu see on üle võetud liikmesriikide seadustesse. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale, ROHS direktiivi VI lisale ja masinadirektiivi II lisale ning see on välja antud tootja vastutusel.
FR	Nous soussigné(e)s, déclarons par la présente que le(s) dispositif(s) médical(aux) de diagnostic *in vitro* indiqué(s) ci-dessus est/sont conforme(s) aux dispositions applicables du Règlement (UE) 2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic *in vitro*, aux dispositions applicables de la Directive 2011/65/UE du Parlement européen et du Conseil du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques, aux dispositions applicables de la Directive 2006/42/CE du Parlement européen et du Conseil du 17 mai 2006 relative aux machines et modifiant la Directive 95/16/CE, telles que transposées dans le droit national des États membres. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV, à l'Annexe VI de la Directive ROHS ainsi qu'à l'Annexe II de la Directive Machines sous la seule responsabilité du fabricant.
HR	Mi, niže potpisani, ovim putem izjavljujemo da su gore navedeni *in vitro* dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o *in vitro* dijagnostičkim medicinskim proizvodima; i dodatno primjenjivim odredbama Direktive 2011/65/EU Europskog parlamenta i Vijeća od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi, te primjenjivim odredbama Direktive 2006/42/EZ Europskog parlamenta i Vijeća od 17. svibnja 2006. o strojevima zamjenjujući Direktivu 95/16/EZ kako je pretočeno u zakone država članica. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD, Prilogom VI. Direktive ROHS i Prilogom II. Direktive o strojevima i izdaje se pod isključivom odgovornošću proizvođača.
HU	Alulírottak ezennel kijelentjük, hogy a fent leírt in vitro orvostechnikai eszköz(ök) megfelel(nek) az Európai Parlament és a Tanács in vitro diagnosztikai orvostechnikai eszközökről szóló (EU) 2017/746 (2017. április 5.) rendelete vonatkozó rendelkezéseit; továbbá az Európai Parlament és a Tanács egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról szóló 2011/65/EU (2011. június 8.) irányelve (RoHS irányelv) vonatkozó rendelkezéseit; valamint az Európai Parlament és a Tanács a gépekről és a 95/16/EK irányelv módosításáról szóló 2006/42/EK (2006. május 17.) irányelve vonatkozó rendelkezéseit a tagállamok jogrendjébe átültető rendelkezéseknek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében, a RoHS irányelv VI. mellékletében és a gépekről szóló irányelv II. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.

EN	**We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.** **This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.**
IT	Noi, i sottoscritti, con la presente dichiariamo che il(i) dispositivo(i) medico-diagnostico(i) *in vitro* sopra descritto(i) è(sono) conforme(i) alle disposizioni applicabili del regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medico-diagnostici *in vitro*; è(sono) inoltre conforme(i) alle disposizioni applicabili della direttiva 2011/65/UE del Parlamento europeo e del Consiglio dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche, e alle disposizioni applicabili della direttiva 2006/42/CE del Parlamento europeo e del Consiglio del 17 maggio 2006 relativa alle macchine e che modifica la direttiva 95/16/CE come recepite nelle legislazioni degli Stati membri. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD, all'allegato VI della direttiva ROHS e all'allegato II della direttiva macchine ed è rilasciata sotto la responsabilità esclusiva del fabbricante.
LV	Mēs, apakšā parakstījušies, ar šo paziņojam, ka iepriekš aprakstītā(-s) *in vitro* diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par *in vitro* diagnostikas medicīniskām ierīcēm un papildus prasībām, kas noteiktas Eiropas Parlamenta un Padomes Direktīvā 2011/65/ES (2011. gada 8. jūnijs) par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās un Eiropas Parlamenta un Padomes Direktīvā 2006/42/EK (2006. gada 17. maijs) par mašīnām, un ar kuru groza Direktīvu 95/16/EK, kā tā ieviesta dalībvalstu tiesību aktos. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu, ROHS direktīvas VI pielikumu un Direktīvas par mašīnām II pielikumu un par izdošanu atbild vienīgi ražotājs.
LT	Mes, toliau pasirašiusieji (-iusiosios), pareiškiame, kad anksčiau minėta (-os) *in vitro* diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl *in vitro* diagnostikos medicinos priemonių taikytinas nuostatas; taip pat ji (jos) atitinka 2011 m. birželio 8 d. Europos Parlamento ir Tarybos direktyvos 2011/65/ES dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo taikomas nuostatas ir 2006 m. gegužės 17 d. Europos Parlamento ir Tarybos direktyvos 2006/42/EB dėl mašinų, iš dalies keičiančios Direktyvą 95/16/EB, taikomas nuostatas, perkeltas į valstybių narių teisės aktus. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu, ROHS direktyvos VI priedu ir Mašinų direktyvos II priedu ir yra išduodama tik gamintojo atsakomybe.
NO	Vi, undertegnede, erklærer herved at utstyret til *in vitro*-diagnostikk som er anført ovenfor, er i samsvar med gjeldende bestemmelser i Europaparlaments- og rådsforordning (EU) 2017/746 av 5. april 2017 om medisinsk utstyr til *in vitro*-diagnostikk, og ytterligere overholder gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2011/65/EU av 8. juni 2011 om bruksbegrensninger av visse farlige stoffer i elektrisk og elektronisk utstyr, og til gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2006/42/EF av 17. mai 2006 om maskiner, og endring av direktiv 95/16/EF som innarbeidet i medlemsstatenes lovgivning. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen, vedlegg VI i ROHS-direktivet og vedlegg II i maskindirektivet og er utstedt under produsentens eneansvar.
PL	My, niżej podpisani, niniejszym oświadczamy, że wymieniony(-e) powyżej wyrób(wyroby) medyczny(-e) do diagnostyki in vitro spełnia(-ją) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki in vitro, a ponadto wymagania Dyrektywy 2011/65/UE Parlamentu Europejskiego i Rady z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym, Dyrektywy 2006/42/WE Parlamentu Europejskiego i Rady z dnia 17 maja 2006 r. w sprawie maszyn, zmieniającej Dyrektywę 95/16/WE, w sposób, w jaki zostały one wdrożone do ustawodawstwa państw członkowskich. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR, Załącznikiem VI Dyrektywy ROHS oraz Załącznikiem II Dyrektywy Maszynowej i wydana na wyłączną odpowiedzialność producenta.
PT	Nós, abaixo assinados, declaramos que os dispositivos médicos para diagnóstico *in vitro* descritos acima estão em conformidade com as disposições aplicáveis do Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho, de 5 de abril de 2017, relativo aos dispositivos médicos para diagnóstico *in vitro*; e adicionalmente, em conformidade com as disposições aplicáveis da Diretiva 2011/65/UE do Parlamento Europeu e do Conselho, de 8 de junho de 2011, relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrónicos, e com as disposições aplicáveis da Diretiva 2006/42/CE do Parlamento Europeu e do Conselho, de 17 de maio de 2006, sobre máquinas e que altera a Diretiva 95/16/CE, conforme transposta nas leis dos Estados membros. Esta declaração é feita de acordo com o Anexo IV do Regulamento IVD, o Anexo VI da Diretiva ROHS e o Anexo II da Diretiva relativa às Máquinas e é emitida sob a exclusiva responsabilidade do fabricante.
RO	Subsemnații, declarăm că dispozitivul (dispozitivele) medical(e) pentru diagnostic in vitro descrise mai sus sunt conforme cu dispozițiile aplicabile din Regulamentul (UE) 2017/746 al Parlamentului European și al Consiliului din 5 aprilie 2017 privind Dispozitivele medicale pentru diagnosticul in vitro; și, în plus, respectă dispozițiile aplicabile din Directiva 2011/65/UE a Parlamentului European și a Consiliului din 8 iunie 2011 privind restricția utilizării anumitor substanțe periculoase în echipamentele electrice și electronice și cu dispozițiile aplicabile din Directiva 2006/42/CE a Parlamentului European și a Consiliului din 17 mai 2006 privind utilajele și modificarea Directivei 95/16/CE, transpusă în legile statelor membre. Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD, anexa VI la Directiva ROHS și anexa II la Directiva utilajelor și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpísaní, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) in vitro uvedená(-é) vyššie je (sú) v zhode s príslušnými ustanoveniami Nariadenia Európskeho parlamentu a Rady (EÚ) 2017/746 z 5. apríla 2017 o diagnostických zdravotnických pomôckach in vitro; a že je (sú) ďalej v zhode s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2011/65/EÚ z 8. júna 2011 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach a s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2006/42/ES zo 17. mája 2006 o strojových zariadeniach a o zmene a doplnení Smernice 95/16/ES tak, ako boli transponované do zákonov členských štátov. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD, Prílohou VI k Smernici ROHS a Prílohou II k Smernici o strojových zariadeniach a vydáva sa na výhradnú zodpovednosť výrobcu.
SV	Vi, undertecknade, försäkrar härmed att den eller de medicintekniska produkter för *in vitro*-diagnostik som beskrivs ovan överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets förordning (EU) 2017/746 av den 5 april 2017 om medicintekniska produkter för *in vitro*-diagnostik samt även överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning samt med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2006/42/EG av den 17 maj 2006 om maskiner och om ändring av direktiv 95/16/EG (omarbetning) som införlivats i medlemsstaternas lagstiftning. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen, bilaga VI till ROHS-direktivet samt bilaga II till maskindirektivet och utfärdas under tillverkarens enskilda ansvar.
TR	Biz, aşağıda imzaları bulunan, yukarıda belirtilen in vitro diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli İn Vitro Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu ve ayrıca elektrikli ve elektronik cihazlarda belirli tehlikeli maddelerin kullanımının sınırlandırılmasına ilişkin 8 Haziran 2011 tarihli Konseyin ve 2011/65/EU sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine, makinelere ilişkin 17 Mayıs 2006 tarihli Konseyin ve 2006/42/EC sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine ve üye devlet yasalarına aktarılan 95/16/EC sayılı ek Direktife uygun olduğunu beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV, ROHS Direktifi Ek VI ve Makineler Direktifi Ek II uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altında yayınlanmıştır.

End of form

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0004FU
Basic UDI-DI Name: Detergent B
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
2J94-22	Detergent B	59058	W0201010185

Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 USA
Manufacturer SRN	US-MF-000017777
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue Charlottetown, Prince Edward Island CANADA C1E 2B9
Conformity Assessment Procedure	**Annex II and III**

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

Full Name: Thomas Creel
Function: Sr. Director, Instrument and Automation Quality
Signature: Thomas Creel
Date of Approval: 20-May-2022

Full Name: Michele Smith-Waheed
Function: Associate Director, Regulatory Affairs
Signature: M Smith-Waheed
Date of Approval: 20-May-2022

Signed for, and on behalf of: Abbott Laboratories, 1915 Hurd Drive, Irving, TX 75038

Date Issued: 20-May-2022
Supersedes: N/A

Place Issued: Irving, Texas
Effective (Date or Lot Number): 20-May-2022

EN	EU Declaration of Conformity	Basic UDI-DI	Basic UDI-DI Name
BG	ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ	Базов UDI-DI	Наименование на базов UDI-DI
CS	EU PROHLÁŠENÍ O SHODĚ	Základní UDI-DI	Název základního UDI-DI
DA	EU-OVERENSSTEMMELSESERKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄTSERKLÄRUNG	Basis-UDI-DI	Basis-UDI-DI Name
EL	ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ	Βασικό UDI-DI	Ονομασία βασικού UDI-DI
ES	DECLARACIÓN UE DE CONFORMIDAD	UDI-DI Básico	Nombre UDI-DI Básico
ET	ELi vastavusdeklaratsioon	Põhi-UDI-DI	Põhi-UDI-DI nimi
FR	Déclaration de conformité UE	IUD-ID de base	Nom IUD-ID de base
HR	EU IZJAVA O SUKLADNOSTI	Osnovni UDI-DI	Naziv osnovnog UDI-DI
HU	EU-MEGFELELŐSÉGI NYILATKOZAT	Alapvető UDI-DI	Alapvető UDI-DI neve
IT	Dichiarazione di conformità UE	UDI-DI di base	Nome UDI-DI di base
LV	ES atbilstības deklarācija	Pamata UDI-DI	Pamata UDI-DI nosaukums
LT	ES ATITIKTIES DEKLARACIJA	Bazinis UDI-DI	Bazinio UDI-DI pavadinimas
NO	EU-samsvarserklæring	Grunnleggende UDI-DI	Grunnleggende UDI-DI-navn
PL	DEKLARACJA ZGODNOŚCI UE	Kod Basic UDI-DI	Nazwa kodu Basic UDI-DI
PT	DECLARAÇÃO UE DE CONFORMIDADE	UDI-DI básico	Nome UDI-DI Básico
RO	Declarația de Conformitate UE	UDI-DI de bază	Nume UDI-DI de bază
SK	EÚ VYHLÁSENIE O ZHODE	Základný UDI-DI	Názov základného UDI-DI
SV	EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE	Grundläggande UDI-DI	Namn på grundläggande UDI-DI
TR	AB Uygunluk Beyanı	Temel UDI-DI	Temel UDI-DI İsmi

EN	Risk Class	List Number and Size Code	Product and Trade Name
BG	Клас според риска	Каталожен номер и код на размера	Име на продукта и търговско наименование
CS	Riziková třída	Katalogové číslo a koncové dvojčíslí určující velikost soupravy	Název produktu a obchodní název
DA	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og varemærkenavn
DE	Risikoklasse	Bestellnummer und Größencode	Produkt- und Handelsname
EL	Κατηγορία κινδύνου	Κωδικός Προϊόντος και Κωδικός Συσκευασίας	Προϊόν και Εμπορική Ονομασία
ES	Clase de riesgo	Número de referencia y código de tamaño	Producto y marca comercial
ET	Riskiklass	Katalooginumber ja suurusekood	Toote nimetus ja kaubanimi
FR	Classe de risque	Référence	Nom de produit et de marque
HR	Klasa rizika	Kataloški broj i oznaka pakiranja	Naziv proizvoda i zaštićeni naziv
HU	Kockázati osztály	Listaszám és készletkiszerelés-kód	Termék- és kereskedelmi név
IT	Classe di rischio	Numero di listino e codice formato	Prodotto e nome commerciale
LV	Riska klase	Kataloga numurs un izmēra kods	Produkta nosaukums un tirdzniecības nosaukums
LT	Rizikos klasė	Katalogo numeris ir dydžio kodas	Gaminio ir prekybinis pavadinimai
NO	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og handelsnavn
PL	Klasa ryzyka	Numer katalogowy	Nazwa produktu i nazwa handlowa
PT	Classe de risco	Número de lista e código de apresentação	Produto e nome comercial
RO	Clasă de risc	Număr de listă și cod dimensiune	Denumirea produsului și denumirea comercială
SK	Riziková trieda	Katalógové číslo	Názov produktu a obchodný názov
SV	Riskklass	Listnummer och storlekskod	Produkt och firmanamn
TR	Risk Sınıfı	Liste Numarası ve Boyut Kodu	Ürün ve Ticari İsmi

EN	GMDN Code	EMDN Code	Manufacturer (Name and Address)	Manufacturer SRN
BG	Код GMDN	Код EMDN	Производител (име и адрес)	ЕРН на производителя
CS	Kód GMDN	Kód EMDN	Výrobce (název a adresa)	Jediné registrační číslo výrobce
DA	GMDN-kode	EMDN-kode	Fabrikant (navn og adresse)	Fabrikants SRN
DE	GMDN-Code	EMDN-Code	Hersteller (Name und Adresse)	Hersteller-SRN
EL	Κωδικός GMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κωδικός EMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κατασκευαστής (Όνομα και Διεύθυνση)	SRN (Μοναδικός Αριθμός Μητρώου) Κατασκευαστή
ES	Código GMDN	Código EMDN	Fabricante (nombre y dirección)	SRN (número de registro único) del fabricante
ET	GMDN-kood	EMDN-kood	Tootja (nimi ja aadress)	Tootja unikaalne registreerimisnumber
FR	Code GMDN	Code EMDN	Fabricant (nom et adresse)	Numéro d'enregistrement unique du fabricant
HR	GMDN kod	EMDN kod	Proizvođač (naziv i adresa)	SRN (jedinstveni registracijski broj) proizvođača
HU	GMDN-kód	EMDN-kód	Gyártó (név és cím)	Gyártó egyedi regisztrációs száma (SRN)
IT	Codice GMDN	Codice EMDN	Fabbricante (nome e indirizzo)	SRN (numero di registrazione unico) del fabbricante
LV	GMDN kods	EMDN kods	Ražotājs (nosaukums un adrese)	Ražotāja vienotais reģistrācijas numurs (VRN)
LT	Visuotinės medicinos priemonių nomenklatūros kodas	Europos medicinos priemonių nomenklatūros kodas	Gamintojas (pavadinimas ir adresas)	Gamintojo unikalusis registracijos numeris
NO	GMDN-kode	EMDN-kode	Produsent (navn og adresse)	Produsentens SRN
PL	Kod GMDN	Kod Europejskiej Nomenklatury Wyrobów Medycznych	Producent (nazwa i adres)	Niepowtarzalny numer rejestracyjny producenta
PT	Código GMDN	Código EMDN	Fabricante (Nome e Morada)	Número único de registo do fabricante
RO	Cod GMDN	Cod EMDN	Producător (nume şi adresă)	SRN producător
SK	Kód GMDN	Kód EMDN	Výrobca (Názov a adresa)	Jediné registračné číslo (SRN) výrobcu
SV	GMDN-kod	EMDN-kod	Tillverkare (namn och adress)	Tillverkarens SRN
TR	GMDN Kodu	EMDN Kodu	Üretici (İsim ve Adres)	Üretici SRN'si

EN	Authorized Representative (Name and Address)	Authorized Representative SRN	Produced by (Site of Manufacture) (Name and Address)
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)
CS	Zplnomocněný zástupce (název a adresa)	Jediné registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fabrikationssted) (Navn og adresse)
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Ονομασία και Διεύθυνση)
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootnud (tootmiskoht) (nimi ja aadress)
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)
LT	Įgaliotasis atstovas (pavadinimas ir adresas)	Įgaliotojo atstovo unikalusis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)
RO	Reprezentant autorizat (nume şi adresă)	SRN reprezentant autorizat	Produs de către (locaţie producţie) (nume şi adresă)
SK	Autorizovaný zástupca (názov a adresa)	Jediné registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)

EN	Conformity Assessment Procedure	Annex II and III	Full Name
BG	Процедура за оценка на съответствието	Приложение II и III	Пълно наименование
CS	Postup posuzování shody	Příloha II a III	Celý název
DA	Overensstemmelsesvurderingsprocedure	Bilag II og III	Fulde navn
DE	Konformitätsbewertungsverfahren	Anhang II und III	Vollständiger Name
EL	Διαδικασία αξιολόγησης συμμόρφωσης	Παράρτημα II και III	Πλήρης ονομασία
ES	Procedimiento de evaluación de la conformidad	Anexos II y III	Nombre completo
ET	Vastavushindamismenetlus	II ja III lisa	Täisnimi
FR	Procédure d'évaluation de la conformité	Annexes II et III	Nom complet
HR	Postupak ocjenjivanja sukladnosti	Prilog II. i III.	Puni naziv
HU	Megfelelőségértékelési eljárás	II. és III. melléklet	Teljes név
IT	Procedura di valutazione della conformità	Allegati II e III	Nome completo
LV	Atbilstības novērtēšanas procedūra	II un III pielikums	Pilns nosaukums
LT	Atitikties vertinimo procedūra	II ir III priedai	Vardas ir pavardė
NO	Framgangsmåte for samsvarsvurdering	Vedlegg II og III	Fullt navn
PL	Procedura oceny zgodności	Załącznik II oraz III	Imię i nazwisko
PT	Procedimento de avaliação da conformidade	Anexo II e III	Nome completo
RO	Procedură de evaluare a conformității	Anexa II și III	Numele complet
SK	Postup posudzovania zhody	Príloha II a III	Celý názov
SV	Förfarande för bedömning av överensstämmelse	Bilaga II och III	Fullständigt namn
TR	Uygunluk Değerlendirme Prosedürü	Ek II ve III	Adı Soyadı

EN	Function	Signed for, and on behalf of	Date Issued
BG	Длъжност	Подписано за и от името на	Дата на издаване
CS	Funkce	Podepsáno za a jménem	Datum vydání
DA	Funktion	Underskrevet for og på vegne af	Udstedelsesdato
DE	Funktion	Unterzeichnet für und im Auftrag von	Datum
EL	Λειτουργία	Υπογράφεται για και εκ μέρους του/της	Ημερομηνία έκδοσης
ES	Función	Firmada por, y en nombre de	Fecha
ET	Funktsioon	Alla kirjutanud (kelle poolt ja nimel)	Väljaandmise kuupäev
FR	Fonction	Signé par et au nom de	Date d'établissement
HR	Funkcija	Potpisano za i u ime	Datum izdavanja
HU	Beosztás	Aláíró a következő képviseletében és nevében	Kiadás dátuma
IT	Funzione	Firmato a nome e per conto di	Data di rilascio
LV	Amats	Parakstīts šādas personas vārdā	Izdošanas datums
LT	Pareigos	Subjekto, kurio vardu pasirašoma, pavadinimas	Išdavimo data
NO	Funksjon	Signert for, og på vegne av	Utstedelsesdato
PL	Funkcja	Podpisano w imieniu	Data wydania
PT	Função	Assinado e em nome de	Data de emissão
RO	Funcția	Semnat pentru și în numele	Data eliberării
SK	Funkcia	Podpísané za a v mene	Dátum vydania
SV	Funktion	Undertecknat för och på uppdrag av	Datum för utfärdande
TR	Görevi	Namına ve temsilen imza	Düzenlenme Tarihi

EN	Supersedes	Signature	Date of Approval
BG	Замества	Подпис	Дата на одобрение
CS	Nahrazuje	Podpis	Datum schválení
DA	Erstatter	Underskrift	Godkendelsesdato
DE	Ersetzt	Unterschrift	Datum der Genehmigung
EL	Αντικαθιστά	Υπογραφή	Ημερομηνία έγκρισης
ES	Sustituye	Firma	Fecha de aprobación
ET	Asendab	Allkiri	Heakskiitmise kuupäev
FR	Annule et remplace	Signature	Date de l'autorisation
HR	Zamjenjuje	Potpis	Datum odobrenja
HU	Hatálytalanítja a következő dokumentumot:	Aláírás	Jóváhagyás dátuma
IT	Sostituisce	Firma	Data di approvazione
LV	Aizstāj	Paraksts	Apstiprināšanas datums
LT	Pakeičia	Parašas	Patvirtinimo data
NO	Erstatter	Signatur	Godkjenningsdato
PL	Zastępuje	Podpis	Data zatwierdzenia
PT	Substitui	Assinatura	Data de aprovação
RO	Înlocuitor	Semnătură	Data aprobării
SK	Nahrádza	Podpis	Dátum schválenia
SV	Ersätter	Namnteckning	Datum för godkännande
TR	Yerini aldığı belge	İmza	Onay Tarihi

EN	Place Issued	Effective (Date or Lot Number)
BG	Място на издаване	В сила от/за (дата или номер на партида)
CS	Místo vydání	Účinné od (datum nebo číslo šarže)
DA	Udstedelsessted	Ikrafttrædelse (dato eller lotnummer)
DE	Ort	Gültig ab (Datum oder Chargenbezeichnung)
EL	Τόπος έκδοσης	Σε ισχύ από (Ημερομηνία ή αρ. παρτίδας)
ES	Expedida en	Efectiva (fecha o número de lote)
ET	Väljaandmise koht	Jõustumine (kuupäev või partiinumber)
FR	Lieu d'établissement	Entrée en vigueur (date ou numéro de lot)
HR	Mjesto izdavanja	Stupa na snagu (datum ili broj serije)
HU	Kiadás helye	Hatálybalépés (dátum vagy tételszám)
IT	Luogo di rilascio	Valido da (data o numero di lotto)
LV	Izdošanas vieta	Spēkā no (datums vai partijas numurs)
LT	Išdavimo vieta	Įsigalioja (data arba partijos numeris)
NO	Utstedelsessted	Gjelder fra (dato eller lotnummer)
PL	Miejsce wydania	Obowiązuje od (data lub numer partii)
PT	Local de emissão	Efetividade (Data ou número de lote)
RO	Locul eliberării	Valabilitate (data sau numărul lotului)
SK	Miesto vydania	Účinnosť od (dátum alebo číslo šarže)
SV	Plats för utfärdande	Verkställigt (datum eller lotnummer)
TR	Düzenlendiği Yer	Yürürlük (Tarih veya Lot Numarası)

EN	**We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.** **This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.**
BG	Ние, долуподписаните, с настоящото декларираме, че гореописаното(ите) медицинско(и) изделие(я) за инвитро диагностика отговаря(т) на приложимите разпоредби на Регламент (ЕС) 2017/746 на Европейския парламент и на Съвета от 5 април 2017 г. относно медицинските изделия за инвитро диагностика; освен това отговаря(т) на приложимите разпоредби на Директива 2011/65/ЕС на Европейския парламент и на Съвета от 8 юни 2011 г. относно ограничението на употребата на определени опасни вещества в електрическото и електронното оборудване и на приложимите разпоредби на Директива 2006/42/ЕО на Европейския парламент и на Съвета от 17 май 2006 г. относно машините, и за изменение на Директива 95/16/ЕО, както е транспонирана в националното законодателство на държавите членки. Тази декларация се прави в съответствие с Приложение IV на Регламента за IVD, Приложение VI на Директивата за ограничаване на опасните вещества (ROHS) и Приложение II на Директивата относно машините и за нейното издаване отговорност носи единствено производителят.
CS	My, níže podepsaní, tímto prohlašujeme, že diagnostický(-é) zdravotnický(-é) prostředek (prostředky) in vitro uvedený(-é) výše je (jsou) ve shodě s příslušnými ustanoveními nařízení Evropského parlamentu a Rady (EU) 2017/746 ze dne 5. dubna 2017 o diagnostických zdravotnických prostředcích in vitro; a že je (jsou) dále ve shodě s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2011/65/EU ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních a s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2006/42/ES ze dne 17. května 2006 o strojních zařízeních a o změně směrnice 95/16/ES, jak byla provedena ve vnitrostátním právu členských států. Toto prohlášení je v souladu s Přílohou IV nařízení IVD, Přílohou VI směrnice ROHS a Přílohou II směrnice o strojních zařízeních a je vydáno na výhradní odpovědnost výrobce.
DA	Vi, undertegnede, erklærer herved, at det in vitro-diagnostiske medicinske udstyr, der er beskrevet ovenfor, er i overensstemmelse med de gældende bestemmelser i Europa-Parlamentets og Rådets forordning (EU) 2017/746 af 5. april 2017 om in vitro-diagnostisk medicinsk udstyr, ligesom det overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2011/65/EU af 8. juni 2011 om begrænsning af brugen af visse farlige stoffer i elektrisk og elektronisk udstyr samt overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2006/42/EF af 17. maj 2006 om maskiner og ændring af direktiv 95/16/EF, som det er transponeret i medlemsstaternes lovgivning. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV, ROHS-direktivets bilag VI samt maskindirektivets bilag II og udstedes under fabrikantens eneansvar.
DE	Wir, die Unterzeichner, erklären hiermit, dass das oben beschriebene In-vitro-Diagnostikum/die oben beschriebenen In-vitro-Diagnostika die entsprechenden Bestimmungen der Verordnung (EU) 2017/746 des Europäischen Parlaments und des Rates vom 5. April 2017 über In-vitro-Diagnostika erfüllen und zusätzlich die entsprechenden Bestimmungen der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten sowie der Richtlinie 2006/42/EG des Europäischen Parlaments und des Rates vom 17. Mai 2006 über Maschinen und zur Änderung der Richtlinie 95/16/EG gemäß Umsetzung in den Gesetzen der Mitgliedsstaaten. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung, Anhang VI der RoHS-Richtlinie und Anhang II der Maschinen-Richtlinie und wird unter alleiniger Verantwortung des Herstellers ausgestellt.
EL	Εμείς, οι υπογράφοντες, δηλώνουμε με το παρόν ότι τα προαναφερόμενα διαγνωστικά ιατροτεχνολογικά προϊόντα συμμορφώνονται με τις ισχύουσες διατάξεις του Κανονισμού (ΕΕ) 2017/746 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 5ης Απριλίου 2017 σχετικά με τα in vitro διαγνωστικά ιατροτεχνολογικά προϊόντα και επίσης συμμορφώνονται με τις ισχύουσες διατάξεις της Οδηγίας 2011/65/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 8ης Ιουνίου 2011 σχετικά με τους περιορισμούς στη χρήση συγκεκριμένων επικίνδυνων ουσιών στον ηλεκτρικό και ηλεκτρονικό εξοπλισμό, καθώς και με τις ισχύουσες διατάξεις της Οδηγίας 2006/42/ΕΚ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 17ης Μαΐου 2006 σχετικά με τον μηχανικό εξοπλισμό και την τροποποιητική Οδηγία 95/16/ΕΚ όπως αυτή μεταφέρθηκε στη νομοθεσία των κρατών μελών. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD, το Παράρτημα VI της Οδηγίας ROHS και το Παράρτημα II της Οδηγίας για τον μηχανικό εξοπλισμό και εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή.
ES	Nosotros, los abajo firmantes, por la presente declaramos que el(los) producto(s) sanitario(s) para diagnóstico *in vitro* descrito(s) anteriormente cumple(n) las disposiciones aplicables del reglamento (UE) 2017/746 del Parlamento Europeo y del Consejo del 5 de abril de 2017 sobre productos sanitarios para diagnóstico *in vitro*; y además cumple(n) las disposiciones aplicables de la Directiva 2011/65/EU del Parlamento Europeo y del Consejo del 8 de junio de 2011 sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos, y las disposiciones aplicables de la Directiva 2006/42/EC del Parlamento Europeo y del Consejo del 17 de mayo de 2006 sobre maquinaria, y la Directiva de enmienda 95/16/EC tal y como se ha incorporado en las leyes de los Estados Miembros. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD, Anexo VI de la Directiva ROHS y Anexo II de la Directiva de máquinas y es emitida bajo la exclusiva responsabilidad del fabricante.
ET	Meie, allakirjutanud, kinnitame, et eespool kirjeldatud *in vitro* diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (*in vitro* diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele ning lisaks vastab see kohaldatavatele sätetele Euroopa Parlamendi ja nõukogu 8. juuni 2011. aasta direktiivis 2011/65/EL (teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes) ja Euroopa Parlamendi ja nõukogu direktiivis 2006/42/EÜ, 17. mai 2006, mis käsitleb masinaid ja millega muudetakse direktiivi 95/16/EÜ, nagu see on üle võetud liikmesriikide seadustesse. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale, ROHS direktiivi VI lisale ja masinadirektiivi II lisale ning see on välja antud tootja vastutusel.
FR	Nous soussigné(e)s, déclarons par la présente que le(s) dispositif(s) médical(aux) de diagnostic *in vitro* indiqué(s) ci-dessus est/sont conforme(s) aux dispositions applicables du Règlement (UE) 2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic *in vitro*, aux dispositions applicables de la Directive 2011/65/UE du Parlement européen et du Conseil du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques, aux dispositions applicables de la Directive 2006/42/CE du Parlement européen et du Conseil du 17 mai 2006 relative aux machines et modifiant la Directive 95/16/CE, telles que transposées dans le droit national des États membres. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV, à l'Annexe VI de la Directive ROHS ainsi qu'à l'Annexe II de la Directive Machines sous la seule responsabilité du fabricant.
HR	Mi, niže potpisani, ovim putem izjavljujemo da su gore navedeni *in vitro* dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o *in vitro* dijagnostičkim medicinskim proizvodima; i dodatno primjenjivim odredbama Direktive 2011/65/EU Europskog parlamenta i Vijeća od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi, te primjenjivim odredbama Direktive 2006/42/EZ Europskog parlamenta i Vijeća od 17. svibnja 2006. o strojevima zamjenjujući Direktivu 95/16/EZ kako je pretočeno u zakone država članica. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD, Prilogom VI. Direktive ROHS i Prilogom II. Direktive o strojevima i izdaje se pod isključivom odgovornošću proizvođača.
HU	Alulírottak ezennel kijelentjük, hogy a fent leírt in vitro orvostechnikai eszköz(ök) megfelel(nek) az Európai Parlament és a Tanács in vitro diagnosztikai orvostechnikai eszközökről szóló (EU) 2017/746 (2017. április 5.) rendelete vonatkozó rendelkezéseit; továbbá az Európai Parlament és a Tanács egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról szóló 2011/65/EU (2011. június 8.) irányelve (RoHS irányelv) vonatkozó rendelkezéseit; valamint az Európai Parlament és a Tanács a gépekről és a 95/16/EK irányelv módosításáról szóló 2006/42/EK (2006. május 17.) irányelve vonatkozó rendelkezéseit a tagállamok jogrendjébe átültető rendelkezéseknek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében, a RoHS irányelv VI. mellékletében és a gépekről szóló irányelv II. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.

EN	**We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.** **This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.**
IT	Noi, i sottoscritti, con la presente dichiariamo che il(i) dispositivo(i) medico-diagnostico(i) *in vitro* sopra descritto(i) è(sono) conforme(i) alle disposizioni applicabili del regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medico-diagnostici *in vitro*; è(sono) inoltre conforme(i) alle disposizioni applicabili della direttiva 2011/65/UE del Parlamento europeo e del Consiglio dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche, e alle disposizioni applicabili della direttiva 2006/42/CE del Parlamento europeo e del Consiglio del 17 maggio 2006 relativa alle macchine e che modifica la direttiva 95/16/CE come recepite nelle legislazioni degli Stati membri. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD, all'allegato VI della direttiva ROHS e all'allegato II della direttiva macchine ed è rilasciata sotto la responsabilità esclusiva del fabbricante.
LV	Mēs, apakšā parakstījušies, ar šo paziņojam, ka iepriekš aprakstītā(-s) *in vitro* diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par *in vitro* diagnostikas medicīniskām ierīcēm un papildus prasībām, kas noteiktas Eiropas Parlamenta un Padomes Direktīvā 2011/65/ES (2011. gada 8. jūnijs) par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās un Eiropas Parlamenta un Padomes Direktīvā 2006/42/EK (2006. gada 17. maijs) par mašīnām, un ar kuru groza Direktīvu 95/16/EK, kā tā ieviesta dalībvalstu tiesību aktos. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu, ROHS direktīvas VI pielikumu un Direktīvas par mašīnām II pielikumu un par izdošanu atbild vienīgi ražotājs.
LT	Mes, toliau pasirašiusieji (-iusiosios), pareiškiame, kad anksčiau minėta (-os) *in vitro* diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl *in vitro* diagnostikos medicinos priemonių taikytinas nuostatas; taip pat ji (jos) atitinka 2011 m. birželio 8 d. Europos Parlamento ir Tarybos direktyvos 2011/65/ES dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo taikomas nuostatas ir 2006 m. gegužės 17 d. Europos Parlamento ir Tarybos direktyvos 2006/42/EB dėl mašinų, iš dalies keičiančios Direktyvą 95/16/EB, taikomas nuostatas, perkeltas į valstybių narių teisės aktus. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu, ROHS direktyvos VI priedu ir Mašinų direktyvos II priedu ir yra išduodama tik gamintojo atsakomybe.
NO	Vi, undertegnede, erklærer herved at utstyret til *in vitro*-diagnostikk som er anført ovenfor, er i samsvar med gjeldende bestemmelser i Europaparlaments- og rådsforordning (EU) 2017/746 av 5. april 2017 om medisinsk utstyr til *in vitro*-diagnostikk, og ytterligere overholder gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2011/65/EU av 8. juni 2011 om bruksbegrensninger av visse farlige stoffer i elektrisk og elektronisk utstyr, og til gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2006/42/EF av 17. mai 2006 om maskiner, og endring av direktiv 95/16/EF som innarbeidet i medlemsstatenes lovgivning. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen, vedlegg VI i ROHS-direktivet og vedlegg II i maskindirektivet og er utstedt under produsentens eneansvar.
PL	My, niżej podpisani, niniejszym oświadczamy, że wymieniony(-e) powyżej wyrób(wyroby) medyczny(-e) do diagnostyki in vitro spełnia(-ją) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki in vitro, a ponadto wymagania Dyrektywy 2011/65/UE Parlamentu Europejskiego i Rady z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym, Dyrektywy 2006/42/WE Parlamentu Europejskiego i Rady z dnia 17 maja 2006 r. w sprawie maszyn, zmieniającej Dyrektywę 95/16/WE, w sposób, w jaki zostały one wdrożone do ustawodawstwa państw członkowskich. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR, Załącznikiem VI Dyrektywy ROHS oraz Załącznikiem II Dyrektywy Maszynowej i wydana na wyłączną odpowiedzialność producenta.
PT	Nós, abaixo assinados, declaramos que os dispositivos médicos para diagnóstico *in vitro* descritos acima estão em conformidade com as disposições aplicáveis do Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho, de 5 de abril de 2017, relativo aos dispositivos médicos para diagnóstico *in vitro*; e adicionalmente, em conformidade com as disposições aplicáveis da Diretiva 2011/65/UE do Parlamento Europeu e do Conselho, de 8 de junho de 2011, relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrónicos, e com as disposições aplicáveis da Diretiva 2006/42/CE do Parlamento Europeu e do Conselho, de 17 de maio de 2006, sobre máquinas e que altera a Diretiva 95/16/CE, conforme transposta nas leis dos Estados membros. Esta declaração é feita de acordo com o Anexo IV do Regulamento IVD, o Anexo VI da Diretiva ROHS e o Anexo II da Diretiva relativa às Máquinas e é emitida sob a exclusiva responsabilidade do fabricante.
RO	Subsemnații, declarăm că dispozitivul (dispozitivele) medical(e) pentru diagnostic in vitro descrise mai sus sunt conforme cu dispozițiile aplicabile din Regulamentul (UE) 2017/746 al Parlamentului European și al Consiliului din 5 aprilie 2017 privind Dispozitivele medicale pentru diagnosticul in vitro; și, în plus, respectă dispozițiile aplicabile din Directiva 2011/65/UE a Parlamentului European și a Consiliului din 8 iunie 2011 privind restricția utilizării anumitor substanțe periculoase în echipamentele electrice și electronice și cu dispozițiile aplicabile din Directiva 2006/42/CE a Parlamentului European și a Consiliului din 17 mai 2006 privind utilajele și modificarea Directivei 95/16/CE, transpusă în legile statelor membre. Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD, anexa VI la Directiva ROHS și anexa II la Directiva utilajelor și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpísaní, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) in vitro uvedená(-é) vyššie je (sú) v zhode s príslušnými ustanoveniami Nariadenia Európskeho parlamentu a Rady (EÚ) 2017/746 z 5. apríla 2017 o diagnostických zdravotnických pomôckach in vitro; a že je (sú) ďalej v zhode s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2011/65/EÚ z 8. júna 2011 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach a s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2006/42/ES zo 17. mája 2006 o strojových zariadeniach a o zmene a doplnení Smernice 95/16/ES tak, ako boli transponované do zákonov členských štátov. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD, Prílohou VI k Smernici ROHS a Prílohou II k Smernici o strojových zariadeniach a vydáva sa na výhradnú zodpovednosť výrobcu.
SV	Vi, undertecknade, försäkrar härmed att den eller de medicintekniska produkter för *in vitro*-diagnostik som beskrivs ovan överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets förordning (EU) 2017/746 av den 5 april 2017 om medicintekniska produkter för *in vitro*-diagnostik samt även överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning samt med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2006/42/EG av den 17 maj 2006 om maskiner och om ändring av direktiv 95/16/EG (omarbetning) som införlivats i medlemsstaternas lagstiftning. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen, bilaga VI till ROHS-direktivet samt bilaga II till maskindirektivet och utfärdas under tillverkarens enskilda ansvar.
TR	Biz, aşağıda imzaları bulunan, yukarıda belirtilen in vitro diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli İn Vitro Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu ve ayrıca elektrikli ve elektronik cihazlarda belirli tehlikeli maddelerin kullanımının sınırlandırılmasına ilişkin 8 Haziran 2011 tarihli Konseyin ve 2011/65/EU sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine, makinelere ilişkin 17 Mayıs 2006 tarihli Konseyin ve 2006/42/EC sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine ve üye devlet yasalarına aktarılan 95/16/EC sayılı ek Direktife uygun olduğunu beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV, ROHS Direktifi Ek VI ve Makineler Direktifi Ek II uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altında yayınlanmıştır.

End of form

Abbott

Declaration of Conformity

Certificate Identification: DoC-7D65-SD DLK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D65-22 7D65-42	53027	Gamma-Glutamyl Transferase	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 19 May 2022

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 13-May-2022
Date Issued: 19 May 2022
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 19 May 2022

Abbott

Declaration of Conformity

Certificate Identification: DoC-7D62-SD DLK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7D62-22	53359	Cholesterol	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

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Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 24 May 2022

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Assoc. Director Regulatory Affairs**
Date of Approval: 23-May-2022
Date Issued: 24 May 2022
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 24 May 2022

Abbott

Declaration of Conformity

Certificate Identification: DOC-6L45-SD DLK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6L45-22	53229	Total Bilirubin	**Self-declared**
6L45-42	53229	Total Bilirubin	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue, Charlottetown, Prince Edward Island C1E 2B9, Canada.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

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Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 19 May 2022

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 13-May-2022
Date Issued: 19 May 2022
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 13-Sep-2019
Effective (Date or Lot Number): 19 May 2022

Abbott

Declaration of Conformity

Certificate Identification: DoC-3P68-SD DLK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
3P68-22 3P68-32	46795	Magnesium	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fisher Diagnostics, a division of Fisher Scientific Company, LLC, a part of Thermo Fisher Scientific Inc., 8365 Valley Pike Middletown, VA 22645, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

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Date of Approval: 23-May-2022
Date Issued: 24 May 2022
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 26-Feb-2018
Effective (Date or Lot Number): 24 May 2022

NovaTec Immundiagnostica GmbH

Product List – CE Marked

Certified by

ISO 13485:2016

EC – Directive 98 / 79 EC
For In-Vitro-Diagnostics

2020-02-1

NovaTec Immundiagnostica GmbH

NovaLisa® Virology

Prod. No.	Name
ADVA0010	Adenovirus IgA
ADVG0010	Adenovirus IgG
ADVM0010	Adenovirus IgM
CHIG0590	Chikungunya Virus IgG capture
CHIM0590	Chikungunya Virus IgM µ-capture
CMVG0110	Cytomegalovirus (CMV) IgG
ACMV7110	Avidity Cytomegalovirus (CMV) IgG
CMVM0110	Cytomegalovirus (CMV) IgM
DENG0120	Dengue Virus IgG
DENM0120	Dengue Virus IgM
DVM0640	Dengue Virus IgM µ-capture
NS1D4020	Dengue Virus NS1 Antigen
EBVA0150	Epstein-Barr Virus (VCA) IgA
EBVG0150	Epstein-Barr Virus (VCA) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG
EBVM0150	Epstein-Barr Virus (VCA) IgM
EBVG0580	Epstein-Barr Virus (EBNA) IgG
HANG0670	Hantavirus IgG
HANM0670	Hantavirus IgM
HEVG0780	Hepatitis E Virus (HEV) IgG
HEVM0780	Hepatitis E Virus (HEV) IgM
HSVG0250	Herpes simplex Virus 1+2 (HSV) IgG
HSVM0250	Herpes simplex Virus 1+2 (HSV) IgM
HSV1G0500	Herpes simples Virus 1 (HSV 1) IgG
HSV1M0500	Herpes simplex Virus 1 (HSV 1) IgM
HSV2G0540	Herpes simplex Virus 2 (HSV 2) IgG
HSV2M0540	Herpes simplex Virus 2 (HSV 2) IgM
INFA0290	Influenza Virus A IgA
INFG0290	Influenza Virus A IgG
INFM0290	Influenza Virus A IgM
INFA0300	Influenza Virus B IgA
INFG0300	Influenza Virus B IgG
INFM0300	Influenza Virus B IgM
MEAG0330	Measles Virus IgG
AMEA7330	Avidity Measles Virus IgG
MEAM0330	Measles Virus IgM
MUMG0340	Mumps Virus IgG
MUMM0340	Mumps Virus IgM
PAIA0360	Parainfluenza Virus 1,2,3 IgA
PAIG0360	Parainfluenza Virus 1,2,3 IgG
PARG0370	Parvovirus B 19 IgG
PARM0370	Parvovirus B 19 IgM
RSVA0380	Respiratory syncytial Virus IgA
RSVG0380	Respiratory syncytial Virus IgG
RSVM0380	Respiratory syncytial Virus IgM
RUBG0400	Rubella Virus IgG

ARUB7400	Avidity Rubella Virus IgG
RUBM0400	Rubella Virus IgM µ-capture
TICG0440	TBE / FSME IgG
TICM0440	TBE / FSME IgM
PTICG044	TBE / FSME IgG plus
VZVA0490	Varicella-Zoster Virus (VZV) IgA
VZVG0490	Varicella-Zoster Virus (VZV) IgG
VZVM0490	Varicella-Zoster Virus (VZV) IgM
ZVG0790	Zika Virus IgG capture
ZVM0790	Zika Virus IgM µ-capture

NovaLisa ® Bacteriology

Prod. No.	Name
BAR0900	Bartonella
BOPA0030	Bordetella pertussis IgA
BOPG0030	Bordetella pertussis IgG
BOPM0030	Bordetella pertussis IgM
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
BRUG0050	Brucella IgG
BRUM0050	Brucella IgM
CHLA0070	Chlamydia trachomatis IgA
CHLG0070	Chlamydia trachomatis IgG
CHLM0070	Chlamydia trachomatis IgM
CHLA0510	Chlamydia pneumoniae IgA
CHLG0510	Chlamydia pneumoniae IgG
CHLM0510	Chlamydia pneumoniae IgM
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebycterium diphtheriae toxin 5S IgG plus
COX1G0600	Coxiella burnetii (Q-Fever) Phase 1 IgG
COX2G0600	Coxiella burnetii (Q-Fever) Phase 2 IgG
COX2M0600	Coxiella burnetii (Q-Fever) Phase 2 IgM
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
LEGG0650	Legionella Pneumophila IgG
LEGM0650	Legionella Pneumophila IgM
LEPG0660	Leptospira IgG
LEPM0660	Leptospira IgM

MYCA0350	Mycoplasma pneumoniae IgA
MYCG0350	Mycoplasma pneumoniae IgG
MYCM0350	Mycoplasma pneumoniae IgM
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani toxin 5S IgG
PTETG043	Clostridium tetani toxin 5S IgG plus

NovaLisa ® Parasites

Prod. No.	Name
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
LEIG0310	Leishmania infantum IgG
MAL0620	Malaria
TOXA0460	Toxoplasma gondii IgA
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TOXM0460	Toxoplasma gondii IgM µ-capture

NovaLisa ® Worms

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
ECHG0130	Echinococcus IgG
FIL0760	Filariasis
SCHG0410	Schistosoma mansoni IgG
SCHM0410	Schistosoma mansoni IgM
STRO0690	Strongyloides
TAEG0420	Taenia solium IgG
TOCG0450	Toxocara canis IgG
TRIG0480	Trichinella spiralis IgG

NovaLisa ® Fungi

Prod. No.	Name
ASPG0680	Aspergillus fumigatus IgG
ASPM0680	Aspergillus fumigatus IgM
CANA0060	Candida albicans IgA
CANG0060	Candida albicans IgG
CANM0060	Candida albicans IgM

NovaLisa ® Hormones

THYROID HORMONES
(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
FT41050	Free T4
TSH1030	TSH

Hormones

STEROID HORMONES
(ELISAs for the determination of steroid hormones in plasma and serum)

Prod. No.	Name
DNOV001	Cortisol
DNOV002	Testosterone
DNOV003	17 beta-Estradiol
DNOV004	17-OH Progesterone
DNOV005	DHEA-S
DNOV006	Progesterone
DNOV008	Androstenedione
DNOV009	Free Testosterone
DNOV011	Total Estriol
DNOV012	Aldosterone

STEROID HORMONES IN URINE
(ELISAs for the determination of steroid hormones in urine)

Prod. No.	Name
DNOV010	Urinary Cortisol

STEROID HORMONES IN SALIVA
(ELISAs for the determination of steroid hormones in saliva)

Prod. No.	Name
DSNOV20	Cortisol Saliva
DSNOV21	Testosterone Saliva
DSNOV24	DHEA-S Saliva
DSNOV27	Androstenedione Saliva

PROTEIN HORMONES
(ELISAs for the determination of proteins in plasma and serum)

Prod. No.	Name
DNOV030	LH
DNOV031	FSH
DNOV032	Prolactin
DNOV033	AFP
DNOV034	beta HCG

THYROID HORMONES
(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
DNOV051	Free T3
DNOV053	Total T3
DNOV054	Total T4
DNOV057	Thyroglobulin

DIABETES MONITORING
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV111	Insulin
DNOV112	C-Peptide

CIRCULATING IMMUNO COMPLEXES
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV093	CIC-C1q
DNOV094	CIC-C3d
DNOV096	CH-50

TUMOR MARKERS
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV 060	CEA
DNOV061	CA 125
DNOV062	CA 15-3
DNOV063	CA 19-9

MISCELLANEOUS
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV100	Ferritin
DNOV101	HGH
DNOV102	IgE

NovaLisa ® Autoimmune

Autoimmune
(ELISAs for the determination of specific autoimmune antibodies)

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO

Rheumatology
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
RFM3010	Rheumatoid Factor IgM

NovaLisa ® Recombinant Antigens

Prod. No.	Name
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
HANG0670	Hantavirus IgG
HANM0670	Hantavirus IgM
HELA0220	Helicobacter pylori IgA
PHELA022	Helicobacter pylori IgA plus
HEVG0780	Hepatitis E Virus (HEV) IgG
HEVM0780	Hepatitis E Virus (HEV) IgM
HSV1G0500	Herpes simples Virus 1 (HSV 1) IgG
HSV1M0500	Herpes simplex Virus 1 (HSV 1) IgM
HSV2G0540	Herpes simplex Virus 2 (HSV 2) IgG
HSV2M0540	Herpes simplex Virus 2 (HSV 2) IgM
MAL0620	Malaria
STRO0690	Strongyloides
ZVG0790	Zika Virus IgG capture
ZVM0790	Zika Virus IgM µ-capture

NovaLisa ® Quantitative Assays (WHO standardized)

Prod. No.	Name
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebycterium diphtheriae toxin 5S IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani toxin 5S IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TSH1030	TSH

NovaLisa ® Quantitative Assays

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebacterium diphtheriae toxin 5S IgG plus
FT41050	Free T4
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG
ARUB7400	Avidity Rubella Virus IgG
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani 5S toxin IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TICG0440	TBE / FSME IgG
PTICG044	TBE / FSME IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TSH1030	TSH

Antigen Assays

Prod. No.	Name
NS1D4020	Dengue Virus NS1 Antigen

NovaLisa ® IgM µ-capture Assays

Prod. No.	Name
CHIM0590	Chikungunya Virus IgM µ-capture
DVM0640	Dengue Virus IgM µ-capture
RUBM0400	Rubella Virus IgM µ-capture
TOXM0460	Toxoplasma gondii IgM µ-capture
ZVM0790	Zika Virus IgM µ-capture

NovaLisa ® Antibody Assays

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
LEIG0310	Leishmania infantum IgG
MAL0620	Malaria
STRO0690	Strongyloides
TAEG0420	Taenia solium IgG
TOCG0450	Toxocara canis IgG
TRIG0480	Trichinella spiralis IgG

NovaLisa ® Avidity Assays

Prod. No.	Name
ACMV7110	Avidity Cytomegalovirus (CMV) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG
AMEA7330	Avidity Measles Virus IgG
ARUB7400	Avidity Rubella Virus IgG
ATOX7460	Avidity Toxoplasma gondii IgG

NovaLisa ® Liquor Diagnostic

Prod. No.	Name
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM

Certificate of Registration

nqa global assurance

This is to certify that the Quality Management System of:

Avantor Fluid Handling B.V.

Maidstone 50
5026 SK Tilburg
The Netherlands

applicable to:

The design, engineering, manufacturing and distribution of Single Use Systems and supporting hardware, including installation-, service- and maintenance activities for the pharmaceutical and biotech industry.

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 9001:2015

Certificate Number:	16880
EAC Code:	34
Certified Since:	March 22, 2012
Valid Until:	March 19, 2024
Reissued:	March 20, 2021
Cycle Issued:	March 20, 2021

For and on behalf of NQA, USA

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

Declaration of CE conformity

Avantor Performance Materials B.V. reg. no. 38013066 who is an established manufacturer of Hematology- Reagents, Stains, Controls and Calibrators and products for Histopathology located at:

Teugseweg 20
7418 AM Deventer
The Netherlands

herewith declares the following:

The reagents (see attached list) are labeled with the J.T.Baker® label and have the CE mark on the label where applicable. The devices comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the conformity assessment procedure according to Annex III. The BeneSphera™ 3 Part Diff Analyzer H32 is in compliance with IEC 61010, Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use.
The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self-registration.
This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking.

Deventer, the Netherlands.

January 6, 2015

Dr. J. Mittendorf
QA & RA Manager

J.T.Baker® product list for CE marked products

Product no.	Product	Pack size
Hematology Analyzer		
2983	BeneSphera™ 3-part Diff Hematology Analyzer H32	1 unit
Clinical Chemistry Analyzer		
2946	BeneSphera™ Clinical Chemistry Analyzer C72	1 unit
Diluents		
3961	Diluid 100 Plus	20 liter
2990.9010PC	Diluid™ 22	10 liter
3954	Diluid 590	20 liter
3969	Diluid 610	20 liter
3430.9020	Diluid Abacus	20 liter
3430.9010	Diluid Abacus	10 liter
3996	Diluid AC 900	20 liter
3476.9020PC	Diluid APR	20 liter
3957	Diluid Azide free	20 liter
2901.9010PC	Diluid BS34	10 liter
3963	Diluid III Diff	20 liter
3963.9010	Diluid III Diff	10 liter
3459.9020	Diluid Erma	20 liter
3419.9020PC	Diluid M5	20 liter
3439.9020PC	Diluid Mindray	20 liter
3483.9020PC	Diluid NR	20 liter
2987.9020PC	Diluid Ruby	20 liter
3832.9020	Diluid/Sheath 3200-4000	20 liter
3976	Diluid ST 1600/2000	20 liter
3495.9010PC	Sheath D	10 liter
3471.9020PC	Sheath Fluid 3000/3500	20 liter
Lyses		
3998	CN-free Lyse Diff AC 900	5 liter
3744	CyMet 1000 CN free	5 liter
2986.0500PE	CyMet™ 22	500 ml
3469.9010PC	CyMet 3000	10 liter
3823.1000	CyMet 3200 CN free	1 liter
3839.5000PC	CyMet 3500	5 liter
3825	CyMet 3500 CN free	5 liter
3773.5000PC	CyMet 4500 CN free	5 liter
3975	CyMet 530+ CN free	10 liter
3971	CyMet 590 CN free	5 liter
3970	CyMet 610 CN free	10 liter
3977	CyMet 610 CN free	5 liter
3445.1000PE	CyMet Abacus Baso	1 liter
3431.1000	CyMet Abacus CN free	1 liter
3444.1000PE	CyMet Abacus EO	1 liter
3479.1000PE	CyMet APR Baso II	1 liter
3417.0500PE	CyMet APR CN free	500 ml
3478.1000PE	CyMet APR EO	1 liter
2950.2500PE	CyMet ASA	2.5 liter
2951.0500PE	CyMet ASB	500 ml
2952.9010PC	CyMet AS CN Free	10 liter
3755	CyMet Automated	5 liter
2982.0500PE	CyMet BS3 CN free	500 ml
2902.1000PE	CyMet BS34 CN Free	1 liter
3968.0500	CyMet III Diff	500 ml
3968	CyMet III Diff	1 liter
3964	CyMet III Diff	5 liter
3511.1000	CyMet III Diff CN free	1 liter
3511.5000	CyMet III Diff CN free	5 liter
3416.0500	CyMet Erma	500 ml
3841.1000PE	CyMet H12 CN Free	1 liter
3853.1000	CyMet H20	1 liter
3425.0500	CyMet KX CN Free	500 ml
2985.1000PE	CyMet LH 53	1 liter
3489.1000PE	CyMet MBA	1 liter
3418.1000PE	CyMet MD(I)	1 liter
2984.1000PE	CyMet MD(I) 53	1 liter
3488.0500PE	CyMet MD(II)	500 ml
3497.0500PE	CyMet MH CN Free	500 ml
3852.1000	CyMet Micro	1 liter
3863.1000	CyMet Micro CN free	1L micros
3441.0500PE	CyMet Mindray	500 ml
3440.0500PE	CyMet Mindray CN Free	500 ml
3484.1000PE	CyMet NR III	1 liter
3486.1000PE	CyMet NR III CN Free	1 liter
3485.1000PE	CyMet NR V	1 liter
2988.5000PC	CyMet Ruby CN Free	5 liter
3480.5000PC	CyMet SF Baso	5L
3481.5000PC	CyMet SF Diff 1	5L
3482.0500PE	CyMet SF Diff 2	500 ml
3775.1000	CyMet ST 1600/2000	1 liter
3759.5000	CyMet ST 1600/2000 CN free	5 liter
3759.1000	CyMet ST 1600/2000 CN free	1 liter
3788	CyMet STX/STL	1 liter
3475.5000PC	LeucoLyse	5 liter
2989.5000PC	LeucoLyse Ruby	5 liter
3077	LyzerGlobin™	500 ml
3769	LyzerGlobin	6 x 15 ml
3771	LyzerGlobin PCE	6 x 15 ml
3513.1000PE	RBCLyse™	1 liter
3518G.1000PE	RBCLyse G	1 liter
3514.0500PE	WBCStabilise™	500 ml
Reticulocyte Reagents		
3493.1000PE	RetiClear™ MHG	1 liter
3774	RetiCount™	30 ml
2953.0210PE	RetiCount AS	210 ml
3777	RetiCount CD	15 x 3.5 ml
3494.0200PE	RetiCount G	200 ml
Cleaners		
3507.9020	Blanking Solution Hgb	20 liter
3947	Blanking Solution 1600/2000	20 liter
3763	DetectoTerge™	5 liter
3766	DetectoTerge	1 liter
2970.0900PE	DetectoTerge BS	900 ml
3917	HypoChlorite	5 liter
3900	ProClean™	5 liter
3768.1000	ProClean	1L micros
3432.1000PE	ProClean Abacus	1 liter
3432.5000	ProClean Abacus	5 liter
3902.0100PE	ProClean CD	100 ml
3862.9020PC	ProClean Extra	20 liter
3862.5000	ProClean Extra	5 liter
3862.1000	ProClean Extra	1 liter
3867.1000PE	ProClean Extra	1L micros
3498.1000PE	ProClean MX5	1 liter
3901	ProClean Plus	100 ml
3442.5000PE	Rinse Mindray	5 liter

Product no.	Product	Pack size
Reagent Packs		
2910	Reagent Pack BS34	1 pack
Hematology Controls and Calibrators		
3427/3428/3429	8-Parameter Control L/N/H	2.5 ml
3463/3464/3465	8-Parameter Control L/N/H	2.5 ml
3701/3702/3703	8-Parameter Control L/N/H	4.5 ml
3746	8-Parameter Control L+N+H	3 x 2.5 ml
3747	8-Parameter Control 4xN	4 x 2.5 ml
3751	8-Parameter Control 1xL+4xN+1xH	6 x 2.5 ml
3633/3634/3635	8-Parameter Control ext L/N/H	2.5 ml
3433/3434/3435	3-Diff Control L/N/H	2.5 ml
3502/3503/3504	3-Diff Control L/N/H	4.5 ml
3466	3-Diff Control 4xL	4 x 2.5 ml
3467	3-Diff Control 4xN	4 x 2.5 ml
3468	3-Diff Control 4xH	4 x 2.5 ml
3421/3422/3423	3-Diff Control ext L/N/H	2.5 ml
3681/3682/3683	5D Control L/N/H	5.0 ml
3684/3685/3686	ADV-Diff Control L/N/H	3.5 ml
3613/3614/3615	BC-Diff 5 Control L/N/H	4.5 ml
3940	Cal Set 1	2 x 2.5 ml
3452/3453/3454	CD-Diff Control L/N/H	3.0 ml
3838	CD-Diff Control 2xL+2xN+2xH	6 x 3.0 ml
3455/3456/3457	K-Diff Control L/N/H	2.5 ml
3424	Platelet Control Ext. value	5 x 3 ml
3693/3694/3695	SF-Diff Control L/N/H	4.5 ml
3698/3699	WBC reduced RBC Control L/H	3.0 ml
3731/3732/3733	XE-Diff Control L/N/H	4.5 ml
3652/3653/3654	XE-RET Control L/N/H	3.0 ml

Product no.	Product	Pack size
Stains and Dyes		
3800.1000PE	Eosin-Y Alcoholic	1 liter
3800.2500PE	Eosin-Y Alcoholic	2.5 liter
3800.9200	Eosin-Y Alcoholic	200 liter
3446.1000PE	Eosin Y 0.5% Aqueous	1 liter
3446.9200	Eosin Y 0.5% Aqueous	200 liter
3856.0100	Giemsa	0.1 liter
3856.0500	Giemsa	0.5 liter
3856.1000	Giemsa	1 liter
3856.2500	Giemsa	2.5 liter
3856.9180ST	Giemsa	180 liter
3870.1000	Hematoxyline (Mayer)	1 liter
3870.2500	Hematoxyline (Mayer)	2.5 liter
3873.1000	Hematoxyline (Harris, Gill II)	1 liter
3873.2500	Hematoxyline (Harris, Gill II)	2.5 liter
3873.9200	Hematoxyline (Harris, Gill II)	200 liter
3879.1000	Leishman	1 liter
3855.0500	May Grünwald	500 ml
3855.1000	May Grünwald	1 liter
3855.2500	May Grünwald	2.5 liter
3554.1000PE	Papanicolaou Solution 2A	1 liter
3554.2500PE	Papanicolaou Solution 2A	2.5 liter
3554.9200PE	Papanicolaou Solution 2A	200 liter
3555.1000PE	Papanicolaou Solution 2B	1 liter
3555.2500PE	Papanicolaou Solution 2B	2.5 liter
3556.1000PE	Papanicolaou Solution 3B	1 liter
3556.2500PE	Papanicolaou Solution 3B	2.5 liter
3556.9200PE	Papanicolaou Solution 3B	200 liter
3876.1000	Shorr	1 liter
3878.1000	Wright	1 liter
Clearing agent		
3905.2500PE	UltraClear™	2.5 liter
3905.5000PE	UltraClear	5 liter
3905.9010PE	UltraClear	10 liter
3905.9200	UltraClear	200 liter
Mounting media		
3921.0500	UltraKitt™	500 ml
3921.0600	UltraKitt	6 x 100 ml
3921.9025ST	UltraKit	25 liter
3882.0500	Mounting Medium High	500 ml
3883.0500	Mounting Medium Low	500 ml
Fixatives		
3933.1000	10% v/v Buffered Formaldehyde	1 liter
3933.5000PC	10% v/v Buffered Formaldehyde	5 liter
3933.9010PE	10% v/v Buffered Formaldehyde	10 liter
3933.9020	10% v/v Buffered Formaldehyde	20 liter
3933.9200	10% v/v Buffered Formaldehyde	200 liter
3880.1000	Bouin's Fixative	1 liter
3869.1200	Cervix Fixative	12 x 125 ml
3884.9010PC	Cytology Fixative LBCM	10 liter
3409.9010	Immuno PBS 20x concentrated	10 liter
3059	PBS, diluting fluid for bloodgrouping	20 liter
3059.9010PC	PBS, diluting fluid for bloodgrouping	10 liter

Liofilchem®

DICHIARAZIONE DI CONFORMITÀ CE / EC DECLARATION OF CONFORMITY

DICHIARAZIONE DI CONFORMITÀ CE

La società Liofilchem® S.r.l., con Sede Legale in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italia, in qualità di fabbricante del dispositivo medico-diagnostico *in vitro* elencato nella tabella allegata Revisione 31.0 del 08.01.2016

dichiara sotto la propria responsabilità

1. che il dispositivo sopra indicato soddisfa tutte le disposizioni applicabili della Direttiva 98/79/CE (Allegato III) recepita nella Legislazione Italiana dal Decreto Legislativo n° 332 del 8 settembre 2000;
2. che il dispositivo in oggetto non è incluso nell'Allegato II, lista A e B della Direttiva 98/79/CE
3. che la documentazione tecnica di cui all'allegato III della direttiva Direttiva 98/79/CE è a disposizione delle autorità nazionali presso la sua sede e sarà conservata per 5 anni dall'ultima data di fabbricazione del prodotto;
4. che il processo di fabbricazione segue adeguati principi di assicurazione della qualità;
5. di aver attivato e di mantenere aggiornato, un sistema di sorveglianza post-produzione per il monitoraggio dei prodotti;
6. che il dispositivo in oggetto è stato messo in commercio munito di marcatura CE.

EC DECLARATION OF CONFORMITY

The company Liofilchem® S.r.l., registered office in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italy, as a manufacturer of the in vitro medical-diagnostic device listed in the attached table, Revision 31.0 of 08.01.2016

hereby certifies under its own responsibility

1. that the above mentioned device complies with all the applicable provisions of Directive 98/79/EC (Annex III) and its relevant transposition into national law;
2. the above mentioned is not included in Annex II , List A and B of Directive 98/79/EC;
3. that the technical documentation referred to at Annex III of the Directive 98/79/EC is available for the national authorities in its facility and that this documentation shall be kept for 5 years after the last product has been manufactured;
4. that the manufacturing process follows suitable principles of quality assurance;
5. that, has implemented and keep up to date, a post-production surveillance system for monitoring the products;
6. that the device in question, was introduced into the market provided with CE mark.

Digitally signed by Caicovschi Tudor
Date: 2023.02.16 13:26:46 EET
Reason: MoldSign Signature
Location: Moldova

Roseto, 08.01.2016

Direttore Tecnico/ Technical Director
Dott. Silvio Brocco

10002	DNA AGAR + BLU DI TOLUIDINA
10004	CLED ANDRADE AGAR
10004*	CLED ANDRADE AGAR
10005	MAC CONKEY SORBITOL AGAR
10005*	MAC CONKEY SORBITOL AGAR
10006	TRYPTIC SOY AGAR + 0,6% YEAST EXTRACT
10007	BACILLUS CEREUS AGAR (PEMBA)
10007*	BACILLUS CEREUS AGAR (PEMBA)
10011	YEAST GLUCOSE CHLORAMPHENICOL AGAR
10011*	YEAST GLUCOSE CHLORAMPHENICOL AGAR
10013	DNase TEST AGAR
10013*	DNase TEST AGAR
10014	Purple Lactose Agar
10014*	Purple Lactose Agar
10017	CZAPEK DOX AGAR
10018	DRIGALSKY LACTOSE AGAR
10021	BIGGY (NICKERSON) AGAR
10021*	BIGGY (NICKERSON) AGAR
10022	BRILLIANT GREEN AGAR
10022*	BRILLIANT GREEN AGAR
10023	Chocolate Agar
10023*	Chocolate Agar
10024	TRYPTOSE AGAR
10024*	TRYPTOSE AGAR
10025	COLUMBIA AGAR (Horse Blood 5%)
10025*	COLUMBIA AGAR (Horse Blood 5%)
10026	CLED AGAR
10026*	CLED AGAR
10027	BACILLUS CEREUS AGAR (Mossel)
10027*	BACILLUS CEREUS AGAR (Mossel)
10028	ISOSENSITEST AGAR
10028*	ISOSENSITEST AGAR
10029	MAC CONKEY AGAR
10029*	MAC CONKEY AGAR
10030	MANNITOL SALT AGAR
10030*	MANNITOL SALT AGAR
10031	MUELLER HINTON II AGAR
10031*	MUELLER HINTON II AGAR
10033	PSEUDOMONAS (CETRIMIDE) AGAR
10033*	PSEUDOMONAS (CETRIMIDE) AGAR
10035	SABOURAUD AGAR
10035*	SABOURAUD AGAR
10035S	SABOURAUD AGAR Irradiated
10036	S.S. AGAR
10036*	S.S. AGAR
10037	TRYPTIC SOY AGAR
10037*	TRYPTIC SOY AGAR
10037S	TRYPTIC SOY AGAR Irradiated
10039	ROGOSA AGAR
10039*	ROGOSA AGAR
10040	NEW YORK CITY AGAR
10040*	NEW YORK CITY AGAR
10041	LISTERIA PALCAM AGAR
10041*	LISTERIA PALCAM AGAR
10042	CRYSTAL VIOLET AGAR (Sheep Blood 5%)
10042*	CRYSTAL VIOLET AGAR (Sheed 5%)
10043	HEKTOEN ENTERIC AGAR
10043*	HEKTOEN ENTERIC AGAR
10044	NUTRIENT AGAR
10044*	NUTRIENT AGAR
10046	SERUM TELLURITE AGAR
10047	BISMUTH SULFITE AGAR
10047*	BISMUTH SULFITE AGAR
10048	E.M.B. LEVINE AGAR
10048*	E.M.B. LEVINE AGAR
10050	CAMPYLOBACTER AGAR (Sheep Blood 5%)
10050*	CAMPYLOBACTER AGAR (Sheep Blood 5%)
10051	Legionella BCYE Agar
10051*	Legionella BCYE Agar
10052	YERSINIA SELECTIVE AGAR
10052*	YERSINIA SELECTIVE AGAR
10053	WILKINS CHALGREEN AGAR
10053*	WILKINS CHALGREEN AGAR
10054	WURTZ LACTOSE AGAR
10054*	WURTZ LACTOSE AGAR
10056	X.L.D. AGAR
10056*	X.L.D. AGAR
10057	BILE AESCULIN AGAR
10057*	BILE AESCULIN AGAR
10058S	TRYPTIC SOY AGAR Irradiated -30 mL-
10060	BRAIN HEART INFUSION AGAR
10060*	BRAIN HEART INFUSION AGAR
10064	CHRISTENSEN UREA AGAR
10065	SCHAEDLER KKV AGAR(Sheep Blood 5%)
10065*	SCHAEDLER KKV AGAR(Sheep Blood 5%)
10067	SCHAEDLER KVN AGAR (Sheep Blood 5%)
10069	X.L.T. 4 AGAR
10069*	X.L.T. 4 AGAR
10074S	TRYPTIC SOY AGAR+NEUTRALIZING Irradiated
10078	MUELLER HINTON II MOD. AGAR
10078*	MUELLER HINTON II MOD. AGAR
10079	CASITONE AGAR
10079*	CASITONE AGAR
10080	HAEMOPHYLUS TEST AGAR
10080*	HAEMOPHYLUS TEST AGAR
10082	HELICOBACTER PYLORI AGAR
10082*	HELICOBACTER PYLORI AGAR
10090	M.R.S. Agar
10090*	M.R.S. Agar
10095	BRAIN HEART AGAR FOR HAEMOPHILUS
10129	MAC CONKEY AGAR MMG
10129*	MAC CONKEY AGAR MMG
10131	Mueller Hinton II Agar (Sheep Blood 5%)
10131*	Mueller Hinton II Agar (Sheep Blood 5%)
10132	MUELLER HINTON FASTIDIOUS AGAR 90 mm
10134	Legionella BMPA Agar
10141	SALMONELLA TEST AGAR
10141*	SALMONELLA TEST AGAR
10142	BLOOD AGAR (Sheep Blood 7%)(ISO 10560)
10142*	BLOOD AGAR (Sheep Blood 7%)(ISO 10560)
10143	Mueller Hinton Agar + 5 % Horse Blood Lysed
10145	CAMPYLOBACTER KARMALI AGAR
10146	CAMPYLOBACTER PRESTON AGAR
10148	CAMPYLOBACTER AGAR (Sheep Blood 10%)
10225	LISTERIA PALCAM AGAR 140 mm
10231	MUELLER HINTON II AGAR 140 mm
10233	R.P.M.I. AGAR
10235	SABOURAUD CAF AGAR + GENTAMICIN
10235*	SABOURAUD CAF AGAR + GENTAMICIN
10236	CLED AGAR 140 mm

10240	SCHAEDLER K AGAR (Sheep Blood 5%) 140mm
10241	SCHAEDLER KKV AGAR(Sheep blood 5%) 140mm
10242	SABOURAUD CAF AGAR 140 mm
10243	SABOURAUD CAF AGAR + GENTAMICIN 140mm
10244	DERMATOPHYTE (D.T.M.) AGAR 140 mm
10245	BRUCELLA BLOOD AGAR w HEMIN AND VITAMIN K1
10246	Chromatic™ MH
10247	Brucella Blood Agar with Hemin and Vitamin K1
10249	Purple Lactose Agar 140 mm
10334	NEOMYCIN BLOOD AGAR (Sheep Blood 5%)
10334*	NEOMYCIN BLOOD AGAR (Sheep Blood 5%)
10335	MUELLER HINTON CHOCOLATE AGAR
10353	BORDET GENGOU AGAR (Sheep Blood 15%)
10353*	BORDET GENGOU AGAR (Sheep Blood 15%)
10405	SCHAEDLER CNA AGAR (Sheep Blood 5%)
10407	VANCOMYCIN SCREEN AGAR
10408	WILKINS CHALGREN AGAR +5% SHEEP BLOOD
10409	CAMPYLOBACTER CCDA AGAR
10410	MUELLER HINTON AGAR w VITALEX
10411	BILE ESCULIN AZIDE AGAR w VANCOMYCIN
10412	Legionella BCYE Agar w/o Cysteine
10413	XLD Agar EP, USP, JP Formulation
10416	MIDDLEBROOK 7H11 AGAR
10424	Legionella BCYE Agar w Vancomycin + Colistin
10425	SCEDOSPORIUM SELECTIVE AGAR
10438	MacConkey Agar No.2
10438*	MacConkey Agar No.2
10439	Group A Selective Strep Agar w/ 5% Sheep Blood
10599	CHROMATIC™ MRSA
10600	OXACILLIN RESISTANCE STAPHYLOCOCCUS AGAR
10601	CHOCOLATE AGAR w/o VITOX
10602	CAMPYLOBACTER SKIRROW AGAR
10605	HELICOBACTER PYLORI EGG YOLK EMULSION AGAR
10620	O.A.LISTERIA
11023	CHOCOLATE BACITRACIN AGAR
11023*	CHOCOLATE BACITRACIN AGAR
11024	COLUMBIA CNA AGAR (Sheep Blood 5%)
11024*	COLUMBIA CNA AGAR (Sheep Blood 5%)
11025	COLUMBIA AGAR (Sheep Blood 5%)
11025*	COLUMBIA AGAR (Sheep Blood 5%)
11027	DESOXYCHOLATE AGAR
11027*	DESOXYCHOLATE AGAR
11030	ANAEROBIC AGAR
11033	PSEUDOMONAS ISOLATION AGAR
11033*	PSEUDOMONAS ISOLATION AGAR
11035	SABOURAUD CAF AGAR
11035*	SABOURAUD CAF AGAR
11035S	SABOURAUD CAF AGAR Irradiated
11037	TRYPTIC SOY AGAR (Sheep Blood 5%)
11037*	TRYPTIC SOY AGAR (Sheep Blood 5%)
11038	TRYPTIC SOY AGAR (Horse Blood 5%)
11038*	TRYPTIC SOY AGAR (Horse Blood 5%)
11040	THAYER MARTIN AGAR
11040*	THAYER MARTIN AGAR
11041	AZIDE AGAR (Sheep Blood 5%)
11041*	AZIDE AGAR (Sheep Blood 5%)
11052	DERMATOPHYTE (D.T.M.) AGAR
11052*	DERMATOPHYTE (D.T.M.) AGAR
11054	GARDNERELLA AGAR (Sheep Blood 5%)
11054*	GARDNERELLA AGAR (Sheep Blood 5%)

11057	ENTEROCOCCO AGAR
11057*	ENTEROCOCCO AGAR
11058	SLANETZ BARTLEY AGAR(m-ENTEROCOCCUS)
11058*	SLANETZ BARTLEY AGAR(m-ENTEROCOCCUS)
11060	CLOSTRIDIUM AGAR (Sheep Blood 5%)
11060*	CLOSTRIDIUM AGAR (Sheep Blood 5%)
11065	SCHAEDLER K AGAR (Sheep Blood 5%)
11065*	SCHAEDLER K AGAR (Sheep Blood 5%)
11070	MYCOSEL AGAR
11070*	MYCOSEL AGAR
11132	MUELLER HINTON FASTIDIOUS AGAR (140mm)
11124	COLUMBIA CNA MOD. AGAR (Sheep blood 5%)
11124*	COLUMBIA CNA MOD. AGAR (Sheep blood 5%)
11135	SABOURAUD AGAR MODIFIED
11135*	SABOURAUD AGAR MODIFIED
11143	HERELLEA AGAR
11143*	HERELLEA AGAR
11185	VOGEL JOHNSON AGAR
11185*	VOGEL JOHNSON AGAR
11195	T.C.B.S. AGAR
11195*	T.C.B.S. AGAR
11196	SPS AGAR
11196*	SPS AGAR
11200	PAR TEST AGAR
11200*	PAR TEST AGAR
11205	MYCOPLASMA AGAR
11206	Mueller Hinton II Agar + 2% NaCl
11231	Mueller Hinton II Agar (Sheep Blood 5%) 140mm
11235	SABOURAUD CAF AGAR + TTC
11235*	SABOURAUD CAF AGAR + TTC
11236	Sabouraud CAF Agar + Actidione
11250	TINSDALE AGAR
11250*	TINSDALE AGAR
11335	SABOURAUD AGAR + GENTAMICIN
11335*	SABOURAUD AGAR + GENTAMICIN
11501	ENTEROCOCCUS AGAR + VANCOMYCIN
11506	BURKHOLDERIA CEPACIA SELECTIVE AGAR
11509	R.P.M.I. AGAR
11510	M.HINTON+GLUCOSE+METHYLEN BLUE
11511	NEISSERIA-MORAXELLA MEDIUM
11512	NUTRIENT AGAR acc.to ISO 21528
11513	NUTRIENT AGAR acc.to ISO 6579
11517	COLUMBIA AGAR(Sheep Blood 5%)+VANCOMYCIN
11518	Mueller Hinton Agar + Cloxacillin
11610	Chromatic™ E.coli O157
11611	CHROMATIC™ DETECTION
11612	CHROMATIC™ CANDIDA
11614	CHROMATIC™ SALMONELLA
11616	CHROMATIC™ STAPH AUREUS
11617	CHROMATIC™ STREPTO B
11618	CHROMATIC™ MH
11619	CHROMATIC™ CRE
11621	CHROMATIC™ VRE
11622	CHROMATIC™ ESBL
11627	Chromatic™ Enterococcus
11629	CHROMATIC™ ESBL + AmpC
11629*	CHROMATIC™ ESBL + AmpC
11631	Chromatic™ OXA-48
11632	Chromatic™ Clostridium difficile
11634	Chromatic™ Detection opaque

12031	MUELLER HINTON II AGAR (120X120 mm)
12032	Mueller Hinton II Agar (Sheep Blood 5%) (120 mm x 120 mm)
12033	Mueller Hinton Fastidious Agar (Horse blood 5% + 20 mg/L β-NAD) (120 mm x 120 mm)
13012	CLED/MACCONKEY/TSA BLOOD AGAR
13012*	CLED/MACCONKEY/TSA BLOOD AGAR
13013	BAIRD PARKER/BIGGY/MACCONKEY
13013*	BAIRD PARKER/BIGGY/MACCONKEY
13014	COLUMBIA CNA/CIOCCOLATO/THAYER MARTIN
13014*	COLUMBIA CNA/CIOCCOLATO/THAYER MARTIN
13017	CLED/MACCONKEY MMG/MALTO
13017*	CLED/MACCONKEY MMG/MALTO
13018	BROM CRESOL PURPLE/COLUMBIA CNA/M.CONKEY
13018*	BROM CRESOL PURPLE/COLUMBIA CNA/M.CONKEY
13019	CLED/MACCONKEY/CETRIMIDE
13019*	CLED/MACCONKEY/CETRIMIDE
13020	MAC CONKEY/B.PARKER/TSA BLOOD
13345	GARDNERELLA V./ROGOSA/THAYER MARTIN
13345*	GARDNERELLA V./ROGOSA/THAYER MARTIN
13356	Gard.V. / Chocolate / Thayer Martin
13371	BAIRD PARKER/MACCONKEY/SABOURAUD CAF
13371*	BAIRD PARKER/MACCONKEY/SABOURAUD CAF
13480	MACCONKEY/VOGEL JOHNSON/SABOURAUD
13480*	MACCONKEY/VOGEL JOHNSON/SABOURAUD
13602	SABOURAUD CAF/BAIRD PARKER/BILE ESCULINE
13602*	SABOURAUD CAF/BAIRD PARKER/BILE ESCULINE
13607	CHOC. BAC./COLUMBIA/MAC CONKEY
13607*	CHOC. BAC./COLUMBIA/MAC CONKEY
13614	CLED/MACCONKEY/ENTEROCOCCO
13614*	CLED/MACCONKEY/ENTEROCOCCO
165312	MYCOPLASMA AGAR
18007	CHROMATIC™ STAPH AUREUS/ MRSA
18008	TSA BLOOD/CROMagar ORIENTATION
18008*	TSA BLOOD/CROMagar ORIENTATION
18009	Chromatic™ Salmonella/Hektoen Enteric
18011	CHROMATIC™ DETECTION/ESBL
18012	BRILLIANT GREEN / SS AGAR
18012*	BRILLIANT GREEN / SS AGAR
18015	BIGGY (NICKERSON) / MALT AGAR
18015*	BIGGY (NICKERSON) / MALT AGAR
18017	COLUMBIA CNA BLOOD/CHROMAGAR
18017*	COLUMBIA CNA BLOOD/CHROMAGAR
18018	MAC CONKEY/ SABOURAUD CAF
18020	EMB LEVINE / TSA BLOOD
18020*	EMB LEVINE / TSA BLOOD
18021	Chromatic™ CRE / Chromatic™ ESBL
18021*	Chromatic™ CRE / Chromatic™ ESBL
18022	TSA Blood/Columbia CNA
18327	COLUMBIA CNA / MAC CONKEY
18327*	COLUMBIA CNA / MAC CONKEY
18379	GARDNERELLA V. / THAYER MARTIN
18379*	GARDNERELLA V. / THAYER MARTIN
18380	MAC CONKEY / TSA BLOOD
18380*	MAC CONKEY / TSA BLOOD
18390	BAIRD PARKER / SABOURAUD CAF
18390*	BAIRD PARKER / SABOURAUD CAF
18391	HEKTOEN ENTERIC / YERSINIA
18391*	HEKTOEN ENTERIC / YERSINIA
18422	COLUMBIA CNA / GARDNERELLA
18422*	COLUMBIA CNA / GARDNERELLA

18500	BAIRD PARKER / MAC CONKEY
18500*	BAIRD PARKER / MAC CONKEY
18502	CLED / MAC CONKEY
18502*	CLED / MAC CONKEY
18503	HEKTOEN ENTERIC / SS
18503*	HEKTOEN ENTERIC / SS
18505	MAC CONKEY / S.S.AGAR
18505*	MAC CONKEY / S.S.AGAR
18507	COLUMBIA CNA / CHOCOLATE
18507*	COLUMBIA CNA / CHOCOLATE
18595	D.T.M. / SABOURAUD
18595*	D.T.M. / SABOURAUD
18700	Group A Selective/TSA II + Sheep Blood 5%
18703	CHOCOLATE AGAR /THAYER MARTIN
20075	MAC CONKEY BROTH(7516MC2) 20x5ml
20077	PHYSIOLOGICAL SOLUTION 2.5 ml
20079	PHYSIOLOGICAL SOLUTION 4.5 ML
20081	INOCULUM SOLUTION 5 ML
20089	SUSPENSION BROTH
20090	HELICOBACTER PYLORI TEST
20095	PHYSIOLOGICAL SOLUTION
20098	PEPTONE WATER
20105	Glucose Broth
20121	INOCULUM BROTH 7 ML
20129	TRYPTIC SOY BROTH 15 ml
20136	TRYPTONE WATER
20140	PURPLE LACTOSE BROTH
20156	SUSPENSION MEDIUM 7 ML
20158	MYCOPLASMA TRANSPORT BROTH
20159	TRICHOMONAS BROTH w/o CLORAMPHENICOL
20171	Thioglycollate Medium w Vit.K1 & Hemin
20340	VAGITUBE
21104	TRYPTIC SOY BROTH
21110	SELENITE BROTH
21241	Fluid Thioglycollate Medium
22130	SCHAEDLER BROTH
23001	F.B. FASTIDIOUS BROTH
23002	MUELLER HINTON BROTH w HORSE BLOOD (11ml)
23003	MUELLER HINTON BROTH
24070	MYCOSEL BROTH 20PV
24071	Cooked Meat Medium
24091	HAEMOPHILUS TEST BROTH 20 PV
24098	PEPTONE WATER 20PV
24100	ALKALINE PEPTONE WATER 20PV
24103	NUTRIENT BROTH 20PV
24104	BRAIN HEART INFUSION BROTH 20PV
20105	Glucose Broth
24107	MUELLER HINTON II BROTH 20 PV
24108	MULLER KAUFFMANN BROTH 20PV
24109	SABOURAUD BROTH (Harm.EP) 20PV
24110	SELENITE BROTH 20PV
24111	TODD HEWITT BROTH 20PV
24112	TRYPTOSE BROTH 20PV
24115	TRICHOMONAS BROTH 20PV
24117	Pergola Broth
24119	GN HAJNA BROTH 20PV
24120	BILE AESCULIN BROTH 20PV
24124	Fluid Thioglycollate Medium
24125	SERUM BROTH 20PV
24127	Fluid Thioglycollate Medium + 1% Tween 80

24128	TRYPTIC SOY BROTH + TWEEN 80 1% 20PV
24135	SALMONELLA DIFFERENTIAL BROTH 20PV
24136	TRYPTONE WATER 20PV
24137	MALONATE BROTH 20PV
24139	LYSINE DECARBOXYLASE BROTH 20PV
24141	BRAIN HEART INFUSION BROTH 2 ml 20PV
24142	PHYSIOLOGICAL SOLUTION 3ml 20PV
24144	TODD HEWITT w Gentam/Nalidixic acid 20PV
24145	TODD HEWITT B. w Colistin/Nalid.a. 20PV
24146	THIOGLYCOLLATE M w/o INDICATOR acc.USP 20PV
24147	Thiogycollate Bile
24149	MR-VP MEDIUM 20PV
24161	Sabouraud Dextrose Broth + CAF
24241	Fluid Thioglycollate Medium
24342	MOTILITY TEST MEDIUM 20PV
24345	O.F. Medium with Glucose
24400	RAPPAPORT VASSILIADIS SOY (RSV) BROTH 20PV
24403	BIOTONE BROTH 20PV
24404	CAMPYLOBACTER BROTH 20PV
24411	S.F. BROTH 20PV
24412	STREPTOCOCCUS BROTH 20PV
24413	MOSSEL AND MARTIN w MANNITOL 20PV
24416	UREA BROTH 20PV
24417	Wilkins Chalgren Broth
24430	SCHAEDLER BROTH 20PV
24432	YERSINIA BROTH 20PV
24433	EUGON BROTH 20PV
24436	MIDDLEBROOK 7H9 BROTH 20PV
24446	PHENOL RED BROTH 20PV
24450	Rappaport Broth w/o Soy
24451	Tetrathionate Broth
24459	CASO BROTH (Double Concentration) CE 20PV
24461	RPMI Broth
24462	RPMI Broth (double strength)
24513	TRYPTIC SOY BROTH (Harm.EP)
24514	TRYPTIC SOY BROTH
24516	UREA BROTH
26105	Glucose Broth
26124	Fluid Thioglycollate Medium 100 x 10 ml
26400	RAPPAPORT VASSILIADIS SOY (RSV) BROTH
26513	Tryptic Soy Broth
27001	GESA MEDIUM
27500	Triptic Soy Broth
27501	Todd Hewitt Broth
27502	Brain Heart Infusion Broth
27503	Nutrient Broth
29000	CHECK-SET BROTH Irradiated 20 Tests
30007	CAMPYLOBACTER SELECTIVE THIOGLYCOLLATE MEDIUM
30008	CLOSTRIDIUM AGAR (Sheep Blood 5%)
30009	HELICOBACTER PYLORI AGAR
30010	STREPTOCOCCAL KF + TTC AGAR
30011	SIMMONS CITRATE AGAR
30013	NITRATI AGAR
30014	MOSSEL AGAR
30022	T.C.B.S. AGAR
30023	SABOURAUD CAF AGAR
30024	SABOURAUD CAF + ACTIDIONE AGAR
30030	M.R.S. AGAR
30080	BORDET GENGOU AGAR (Sheep Blood 15%)
30081	CHRISTENSEN UREA AGAR

30082	TRYPTIC SOY AGAR
30083	NUTRIENT AGAR
30084	BRAIN HEART INFUSION AGAR
30085	PHENYLALANINE AGAR
30087	KLIGLER IRON AGAR
30088	KLIGLER IRON AGAR + NaCl 2%
30090	Mueller Hinton II Agar
30091	BIGGY (NICKERSON) AGAR
30093	SABOURAUD AGAR
30095	SIM MEDIUM
30096	T.S.I. AGAR
30097	Tryptose Agar
30098	LYSINE IRON AGAR
30099	Chocolate Agar
30116	LOEFFLER MEDIUM
30117	PERGOLA MEDIUM
30118	Lowenstein Jensen Medium
30119	LOWENSTEIN JENSEN MEDIUM w/o GLYCEROL
30121	Stonebrink Medium
30125	DORSET EGG MEDIUM
30368	MIDDLEBROOK 7H10 AGAR
31065	SPS Agar
31075	Mueller Hinton II Agar
31090	Mueller Hinton II Agar
31097	Tryptose Agar
31099	Chocolate Agar
31121	Stonebrink Medium
33040	THAYER MARTIN AGAR
33055	MYCOSEL AGAR
33060	SERUM TELLURITE AGAR
33066	O.N.P.G. AGAR
33085	BILE AESCULIN AGAR
33086	DERMATHOPHYTE (D.T.M.) AGAR
33118	I.U.T.M. MEDIUM
33120	PETRAGNANI MEDIUM
34070	CAMPYLOBACTER AGAR
34071	CYSTINE TRYPTIC AGAR (CTA)
34075	Mueller Hinton II Agar
34121	LOWENSTEIN JENSEN + RIFAMPICIN 15 µg/mL
34121/1	LOWENSTEIN JENSEN + RIFAMPICIN 5 µg/mL
34121/2	LOWENSTEIN JENSEN + RIFAMPICIN 10 µg/mL
34121/3	LOWENSTEIN JENSEN + RIFAMPICIN 25 µg/mL
34121/4	LOWENSTEIN JENSEN + RIFAMPICIN 50 µg/mL
34121/5	LOWENSTEIN JENSEN + RIFAMPICIN 40 µg/mL
34121/6	LOWENSTEIN JENSEN + RIFAMPICIN 20 µg/mL
34122	LOWENSTEIN JENSEN + RIFAPENTIN 9 µg/mL
34123	LOWENSTEIN JENSEN + ISONIAZID 0.1 µg/mL
34123/1	LOWENSTEIN JENSEN + ISONIAZID 0.2 µg/mL l
34123/2	LOWENSTEIN JENSEN + ISONIAZID 1 µg/mL
34123/3	LOWENSTEIN JENSEN + ISONIAZID 5 µg/mL
34123/4	LOWENSTEIN JENSEN + ISONIAZID 10 µg/mL
34124/1	LOWENSTEIN JENSEN + PYRAZINAMIDE 5 µg/mL
34124/2	LOWENSTEIN JENSEN + PYRAZINAMIDE 15 µg/mL
34124/3	LOWENSTEIN JENSEN + PYRAZINAMIDE 20 µg/mL
34124/4	LOWENSTEIN JENSEN+PYRAZINAMIDE 200 µg/mL
34125/1	LOWENSTEIN JENSEN + STREPTOMYCIN 4 µg/mL
34125/2	LOWENSTEIN JENSEN + STREPTOMYCIN 10 µg/mL
34125/3	LOWENSTEIN JENSEN + STREPTOMYCIN 25 µg/mL
34125/4	LOWENSTEIN JENSEN + STREPTOMYCIN 2 µg/mL
34125/5	LOWENSTEIN JENSEN + STREPTOMYCIN 50 µg/mL

34126/1	LOWENSTEIN JENSEN + ETHAMBUTOL 2 µg/mL
34126/2	LOWENSTEIN JENSEN + ETHAMBUTOL 4 µg/mL
34126/3	LOWENSTEIN JENSEN + ETHAMBUTOL 5 µg/mL
34126/4	LOWENSTEIN JENSEN + ETHAMBUTOL 1 µg/mL
34126/5	LOWENSTEIN JENSEN + ETHAMBUTOL 3 µg/mL
34126/6	LOWENSTEIN JENSEN + ETHAMBUTOL 10 µg/mL
34127	LOWENSTEIN JENSEN + AMIKACIN 5 µg/mL
34127/1	LOWENSTEIN JENSEN + AMIKACIN 40 µg/mL
34128/1	LOWENSTEIN JENSEN + OFLOXACIN 5 µg/mL
34128/2	LOWENSTEIN JENSEN + OFLOXACIN 10 µg/mL
34128/3	LOWENSTEIN JENSEN + OFLOXACIN 25 µg/mL
34128/4	LOWENSTEIN JENSEN + OFLOXACIN 2 µg/mL
34128/5	LOWENSTEIN JENSEN + OFLOXACIN 20 µg/mL
34129/1	LOWENSTEIN JENSEN + PAS 1 µg/mL
34129/2	LOWENSTEIN JENSEN + PAS 10 µg/mL
34129/3	LOWENSTEIN JENSEN + PAS 0.5 µg/mL
34129/4	LOWENSTEIN JENSEN + PAS 0.1 µg/mL
34129/5	LOWENSTEIN JENSEN + PAS 5 µg/mL
34130/1	LOWENSTEIN JENSEN + RIFABUTIN 10 µg/mL
34130/2	LOWENSTEIN JENSEN + RIFABUTIN 30 µg/mL
34130/3	LOWENSTEIN JENSEN + RIFABUTIN 50 µg/mL
34131/1	LOWENSTEIN JENSEN+CLARITHROMICIN 4 µg/mL
34131/2	LOWENSTEIN JENSEN+CLARITHROMYCIN 32 µg/mL
34132/1	LOWENSTEIN JENSEN + ETHIONAMIDE 10 µg/mL
34132/2	LOWENSTEIN JENSEN + ETHIONAMIDE 20 µg/mL
34132/3	LOWENSTEIN JENSEN + ETHIONAMIDE 30 µg/mL
34132/4	LOWENSTEIN JENSEN + ETHIONAMIDE 40 µg/mL
34135/1	LOWENSTEIN JENSEN + NICOTINAMIDE 10 µg/mL
34135/2	LOWENSTEIN JENSEN + NICOTINAMIDE 20 µg/mL
34135/3	LOWENSTEIN JENSEN + NICOTINAMIDE 30 µg/mL
34136	LOWENSTEIN JENSEN + PEFLOXACIN 2 µg/mL
34137/1	LOWENSTEIN JENSEN + CYCLOSERINE 30 µg/mL
34137/2	LOWENSTEIN JENSEN + CYCLOSERINE 10 µg/mL
34137/3	LOWENSTEIN JENSEN + CYCLOSERINE 20 µg/mL
34137/4	LOWENSTEIN JENSEN + CYCLOSERINE 40 µg/mL
34137/5	LOWENSTEIN JENSEN + CYCLOSERINE 50 µg/mL
34138/1	LOWENSTEIN JENSEN + CAPREOMYCIN 10 µg/mL
34138/2	LOWENSTEIN JENSEN + CAPREOMYCIN 40 µg/mL
34138/3	LOWENSTEIN JENSEN + CAPREOMYCIN 20 µg/mL
34138/4	LOWENSTEIN JENSEN + CAPREOMYCIN 30 µg/mL
34139/1	LOWENSTEIN JENSEN + CLOFAZIMINE 5 µg/mL
34139/2	LOWENSTEIN JENSEN + CLOFAZIMINE 10 µg/mL
34143/1	LOWENSTEIN JENSEN + KANAMYCIN 10 µg/mL
34143/2	LOWENSTEIN JENSEN + KANAMYCIN 20 µg/mL
34143/3	LOWENSTEIN JENSEN + KANAMYCIN 30 µg/mL
34144	LOWENSTEIN JENSEN + PYRUVATE 0.2%
34145	LOW.JENSEN + PACT
34146/1	Lowenstein Jensen + Levofloxacin 2 µg/ml
35000	LOWENSTEIN JENSEN MEDIUM
35001	LOWENSTEIN JENSEN + ISONIAZID 0.20 µg/mL
35002	LOWENSTEIN JENSEN + ISONIAZID 1 µg/ml
35010	LOWENSTEIN JENSEN + RIFAMPICIN 40 µg/mL
35011	LOWENSTEIN JENSEN + RIFAMPICIN 20 µg/mL
35020	LOWENSTEIN JENSEN + STREPTOMYCIN 4 µg/mL
35021	LOWENSTEIN JENSEN + STREPTOMYCIN 10µg/ml
35030	LOWENSTEIN JENSEN + ETHAMBUTOL 2 µg/mL
35040	LOWENSTEIN JENSEN + ETHIONAMIDE 20 µg/mL
35041	LOWENSTEIN JENSEN + ETHIONAMIDE 30µg/ml
35050	LOWENSTEIN JENSEN + PYRAZINAMIDE 1 µg/mL
35060	LOWENSTEIN JENSEN + KANAMYCIN 20 µg/mL
35061	LOWENSTEIN JENSEN + KANAMYCIN 30µg/ml
35070	LOWENSTEIN JENSEN + PAS 1 µg/mL
35071	LOWENSTEIN JENSEN + PAS 0.5 µg/mL
35080	LOWENSTEIN JENSEN + OFLOXACIN 2 µg/ml
35081	LOWENSTEIN JENSEN + OFLOXACIN 10 µg/ml
35082	LOWENSTEIN JENSEN + OFLOXACIN 40 µg/ml
35090	LOWENSTEIN JENSEN + CAPREOMYCIN 30 µg/ml
35091	LOWENSTEIN JENSEN + CAPREOMYCIN 20 µg/ml
35147	LOWENSTEIN JENSEN + PNB 500 µg/ml
35148	LOWENSTEIN JENSEN + TCH 2 µg/ml
36001/1	IUTM + STREPTOMYCIN 2 µg/mL
36001/2	IUTM + STREPTOMYCIN 4 µg/mL
36001/3	IUTM + STREPTOMYCIN 10 µg/mL
36001/4	IUTM + STREPTOMYCIN 25 µg/mL
36001/5	IUTM + STREPTOMYCIN 50 µg/mL
36002/1	IUTM + ISONIAZID 0.1 µg/mL
36002/2	IUTM + ISONIAZID 0.2 µg/mL
36002/3	IUTM + ISONIAZID 1 µg/mL
36002/4	IUTM + ISONIAZID 5 µg/mL
36002/5	IUTM + ISONIAZID 10 µg/mL
36003/1	IUTM + ETHAMBUTOL 1 µg/mL
36003/2	IUTM + ETHAMBUTOL 2 µg/mL
36003/3	IUTM + ETHAMBUTOL 3 µg/mL
36003/4	IUTM + ETHAMBUTOL 5 µg/mL
36003/5	IUTM + ETHAMBUTOL 10 µg/mL
36004/1	IUTM + RIFAMPICIN 5 µg/mL
36004/2	IUTM + RIFAMPICIN 10 µg/mL l
36004/3	IUTM + RIFAMPICIN 20 µg/mL
36004/4	IUTM + RIFAMPICIN 40 µg/mL
36004/5	IUTM + RIFAMPICIN 50 µg/mL
36005/1	IUTM + RIFABUTIN 10 µg/mL
36005/2	IUTM + RIFABUTIN 20 µg/mL
36005/3	IUTM + RIFABUTIN 30 µg/mL
36005/4	IUTM + RIFABUTIN 40 µg/mL
36005/5	IUTM + RIFABUTIN 50 µg/mL
36006/1	IUTM + CYCLOSERINE 10 µg/mL
36006/2	IUTM + CYCLOSERINE 20 µg/mL
36006/3	IUTM + CYCLOSERINE 30 µg/mL
36006/4	IUTM + CYCLOSERINE 40 µg/mL
36006/5	IUTM + CYCLOSERINE 50 µg/mL
36007/1	IUTM + OFLOXACIN 1.25 µg/mL
36007/2	IUTM + OFLOXACIN 2.5 µg/mL
36007/3	IUTM + OFLOXACIN 10 µg/mL
36007/4	IUTM + OFLOXACIN 25 µg/mL
36007/5	IUTM + OFLOXACIN 50 µg/mL
36008/1	IUTM + PAS 0.1 µg/mL
36008/2	IUTM + PAS 0.5 µg/mL
36008/3	IUTM + PAS 1 µg/mL
36008/4	IUTM + PAS 5 µg/mL
36008/5	IUTM + PAS 10 µg/mL
36009/1	IUTM + PYRAZINAMIDE 10 µg/mL
36009/2	IUTM + PYRAZINAMIDE 30 µg/mL
36009/3	IUTM + PYRAZINAMIDE 50 µg/mL
36009/4	IUTM + PYRAZINAMIDE 70 µg/mL
36009/5	IUTM + PYRAZINAMIDE 90 µg/mL
37000	MIDDLEBROOK 7H11
37001	MIDDLEBROOK 7H11 + AMIKACIN 2 µg/mL
37002	MIDDLEBROOK 7H11 + AMIKACIN 4 µg/mL
37006	MIDDLEBROOK 7H11 + ETHAMBUTOL 7.5 µg/mL
37011	MIDDLEBROOK 7H11 + ETHIONAMIDE 10 µg/mL

37016	MIDDLEBROOK 7H11 + ISONIAZIDE 0.2 µg/mL
37017	MIDDLEBROOK 7H11 + ISONIAZIDE 1 µg/mL
37021	MIDDLEBROOK 7H11 + KANAMYCIN 6 µg/mL
37026	MIDDLEBROOK 7H11 + PAS 8 µg/mL
37031	MIDDLEBROOK 7H11 + PYRAZINAMIDE 25 µg/mL
37036	MIDDLEBROOK 7H11 + RIFABUTIN 1 µg/mL
37037	MIDDLEBROOK 7H11 + RIFABUTIN 0.5 µg/mL
37041	MIDDLEBROOK 7H11 + RIFAMPICIN 1 µg/mL
37046	MIDDLEBROOK 7H11 + STREPTOMYCIN 2 µg/mL
37051	MIDDLEBROOK 7H11 + OFLOXACIN 2 µg/mL
37056	MIDDLEBROOK 7H11 + CYCLOSERINE 30 µg/mL
400020	Fluid Thioglycollate Medium 6 x 100 ml
400120	Fluid Thioglycollate Medium 6 x 300 ml
400220	Fluid Thioglycollate Medium 6 x 1000 ml
401890	BUFFER SOLUTION pH 7 6X100 ml
401930	SPS Agar 6X150 ml
401980	TRYPTONE WATER 6X100 ml
401990	ALKALINE PEPTONE WATER 6X100 ml
402000	NUTRIENT BROTH 6X100 ml
402020	MUELLER HINTON II BROTH 6X100 ml
402030	MULLER KAUFFMANN BROTH 6X100 ml
402040	SABOURAUD BROTH 6X100 ml
402050	Selenite Broth 6X100 ml
402060	SALMONELLA DIFF.BROTH 6X90 ml
402070	TRYPTOSE BROTH 6X100 ml
402120	MRS AGAR 6X100 ml
402130	PEPTONE WATER 6X100 ml
402140	BLOOD AGAR BASE 6X100 ml
402170	AZIDE BLOOD AGAR BASE 6X100 ml
402180	CLED AGAR 6X100 ml
402190	NUTRIENT AGAR 6X100 ml
402200	DERMATHOPHYTE (D.T.M.) AGAR 6X100 ml
402210	COLUMBIA CNA AGAR BASE 6X100 ml
402220	DRIGALSKI LACTOSE AGAR 6X100 ml
402230	HEKTOEN ENTERIC AGAR 6X100 ml
402240	MAC CONKEY AGAR 6X100 ml
402250	MUELLER HINTON II AGAR 6X100 ml
402270	PSEUDOMONAS CETRIMIDE AGAR 6X100 ml
402280	SABOURAUD AGAR 6X100 ml
402290	MANNITOL SALT AGAR 6X100 ml
402300	S.S. AGAR 6X100 ml
402320	TRYPTOSE AGAR 6X100 ml
402330	BRILLIANT GREEN AGAR 6X100 ml
402340	DESOXYCHOLATE AGAR 6X100 ml
402350	E.M.B. LEVINE AGAR 6X100 ml
402360	SALMONELLA RAPID TEST 6X100 ml
402370	SABOURAUD CAF AGAR 6X100 ml
402380	BRAIN HEART INFUSION AGAR 6X100 ml
402430	PEPTONE DILUITIONS 6X100 ml
402450	MAC CONKEY SORBITOL AGAR 6X100 ml
402500	Fluid Thioglycollate Medium + 1% Tween 80
402570	X.L.D. AGAR 6X100 ml
403030	BIOTONE BROTH 6X100 ml
403050	S.I.M. MEDIUM 6X100 ml
403060	UREA INDOLE BROTH 6X100 ml
412010	BRAIN HEART INFUSION BROTH 6X200 ml
412030	SIMMONS CITRATE AGAR 6X200 ml
412040	LYSINE IRON AGAR 6X200 ml
412050	Selenite Broth 6X200 ml
412060	TODD HEWITT BROTH 6X200 ml

412080	TRICHOMONAS BROTH 6X200 ml
412100	CHRISTENSEN UREA AGAR 5X200 ml
412110	TRYPTIC SOY BROTH + TWEEN80 1% 6x200ml
412130	PSEUDOMONAS AGAR BASE 6x200ml
412150	AZIDE BLOOD AGAR BASE 6X200 ml
412170	PHENILALANINE AGAR 6X200 ml
412180	CLED AGAR 6X200 ml
412190	NUTRIENT AGAR 6X200 ml
412210	COLUMBIA CNA AGAR BASE 6X200 ml
412230	HEKTOEN ENTERIC AGAR 6X200 ml
412240	MAC CONKEY AGAR 6X200 ml
412250	MUELLER HINTON II AGAR 6X200 ml
412270	PSEUDOMONAS CETRIMIDE AGAR 6X200 ml
412280	SABOURAUD AGAR 6X200 ml
412290	MANNITOL SALT AGAR 6X200 ml
412300	S.S. AGAR 6X200 ml
412370	SABOURAUD CAF AGAR 6X200 ml
413010	ISOSENSITEST AGAR 6X200 ml
413030	CAMPYLOBACTER AGAR 6X200 ml
413040	CLOSTRIDIUM AGAR BASE 6X200 ml
413080	NUTRIENT AGAR acc. to ISO 6579
414010	PEPTONE WATER pH 8.4 + NaCl 1% 6X225 ml
432050	SELENITE BROTH (DOUBLE CONCENT.) 6X200ml
432080	TRYPTIC SOY BROTH 6X225 ml
432250	D-Nase TEST AGAR 6X200 ml
432290	TRYPTIC SOY AGAR 6X200 ml
442080	TRYPTIC SOY BROTH 6X200 ml
442220	Chocolate Agar 6x 100 ml
442280	SABOURAUD MODIFIED AGAR 6X100 ml
442290	TRYPTIC SOY AGAR 6X100 ml
442300	WURTZ LACTOSE AGAR 6X100 ml
442320	BILE AESCULIN AGAR 6X100 ml
442350	BIGGY (NICKERSON) AGAR 6X100 ml
442490	SPS AGAR 6X100 ml
452060	Fluid Thioglycollate Medium 6 x 100 ml
452080	TRYPTIC SOY BROTH 6X100 ml
452210	COLUMBIA AGAR BASE 6X200 ml
452500	Fluid Thioglycollate Medium + 1% Tween 80 25 x 100 ml
453060	Fluid Thioglycollate Medium 25 x 100 ml
463100	Fluid Thioglycollate Medium 6 x 900 ml
463130	Selenite Broth 6X1000 ml
470010	TRYPTIC SOY AGAR 6X500 ml
470020	Selenite Broth 6X500 ml
470030	DESOXYCHOLATE AGAR 6X500 ml
470040	SABOURAUD AGAR 6X500 ml
470050	NUTRIENT BROTH 6X500 ml
470060	NUTRIENT AGAR 6X500 ml
470070	Mueller Hinton II Agar 6X500 ml
470080	MANNITOL SALT AGAR 6X500 ml
470090	MAC CONKEY AGAR 6X500 ml
470100	COLUMBIA AGAR BASE 6X500 ml
470110	CLED AGAR 6X500 ml
470120	Chocolate Agar 6 x 500 ml
470130	BLOOD AGAR BASE 6X500 ml
470140	BILE AESCULIN AGAR 6X500 ml
470150	TRICHOMONAS BROTH 6X500 ml
470160	DESOXYCHOLATE CITRATE AGAR 6X500 ml
470210	ALKALINE PEPTONE WATER 6X500 ml
470220	CZAPEK DOX AGAR 6X500 ml
470280	DRIGALSKI LACTOSE AGAR 6X500 ml

470290	CARY BLAIR TRANSPORT MEDIUM 6X500 ml
470300	Fluid Thioglycollate Medium 6 x 500 ml
470320	PEPTONE WATER 6X500 ml
470370	TRYPTIC SOY BROTH 6 x 500 ml
471070	SABOURAUD BROTH 6X500 ml
471120	PHYSIOLOGICAL SOLUTION 6X240 ml
473000	PHYSIOLOGICAL SOLUTION 6X500 ml
481110	CHROMATIC™ CANDIDA 6X100 ml
481130	CHROMATIC™ DETECTION 6X100 ml
481140	CHROMATIC™ SALMONELLA 6X100 ml
481160	CHROMATIC™ STAPH AUREUS 6X100 ml
481180	CHROMATIC™ STREP B 6X100ml
482190	Chromatic™ E.coli O157 6 x 200 ml
490010	HEMO-AEROBIC culturing 6X80 ml
490020	HEMO-ANAEROBIC culturing 6X80 ml
490030	HEMO-AEROBIC culturing-Pediatric 6X40 ml
490040	HEMO-ANAEROBIC culturing-Pediatric 6X40ml
490050	HEMO-AEROBIC culturing NEONATAL 6x9 ml
490060	HEMO-ANAEROBIC culturing NEONATAL 6x9 ml
493000	Fluid Thioglycollate Medium 6 x 100 ml
495010	TRYPTIC SOY BROTH 6x100 ml
495020	Fluid Thioglycollate Medium 6 x 100 ml
500142	URITEST PENTA
500152	URITEST
500182	URITEST M
500702	URITEST EF
50020	VAGITEST
50021	DERMATEST
500232	URITEST N
500302	URITEST 2
500402	URITEST MALTO
500412	URITEST EC
51014	URITEST PENTA
51015	URITEST
51018	URITEST M
51020	VAGITEST 120 slide
51021	DERMATEST
51023	URITEST N
51024	URITEST C
51030	URITEST 2
51040	URITEST MALTO
51041	URITEST EC
51070	URITEST EF
51118	URITEST M
51123	URITEST N 500 slide
51130	URITEST 2 500 slide
51140	URITEST MALTO
51170	CLED/MAC CONKEY/ BILE AESCULIN
52115	CLED/MAC CONKEY/SLANETZ 120 slide
52119	URITEST SF 500 slide
610001	BILE AESCULIN AZIDE AGAR
610002	DEXTROSE AGAR
610005	BLOOD AGAR BASE
610006	BORDET GENGOU AGAR BASE
610007	BRAIN HEART INFUSION AGAR
610008	BRAIN HEART INFUSION BROTH
6100085	BRAIN HEART INFUSION BROTH
610009	BRILLIANT GREEN AGAR
610012	CLED AGAR
6100125	CLED AGAR

610013	COLUMBIA AGAR BASE
6100135	COLUMBIA AGAR BASE
610014	DESOXYCHOLATE AGAR
6100145	DESOXYCHOLATE AGAR
610015	DESOXYCHOLATE CITRATE AGAR
610016	DRIGALSKI LACTOSE AGAR
610019	E.M.B. LEVINE AGAR
610021	HEKTOEN ENTERIC AGAR
6100215	HEKTOEN ENTERIC AGAR
610022	G.C. MEDIUM
610023	KLIGLER IRON AGAR
610024	M.R.S. AGAR (ISO/FDIS 15214)
610025	M.R.S. BROTH (ISO/FDIS 15214)
610026	LOWENSTEIN JENSEN MEDIUM
6100265	LOWENSTEIN JENSEN MEDIUM
610027	LYSINE IRON AGAR
610028	MAC CONKEY AGAR
6100285	MAC CONKEY AGAR
610029	MANNITOL SALT AGAR
6100295	MANNITOL SALT AGAR
610032	MR-VP BROTH
610033	MUELLER HINTON AGAR
6100335	MUELLER HINTON AGAR
610034	MUELLER HINTON BROTH
610035	MULLER KAUFFMANN BROTH
610036	NUTRIENT AGAR
610037	NUTRIENT BROTH
6100375	NUTRIENT BROTH
610038	PEPTONE WATER
610039	PHENYLALANINE AGAR
610041	PSEUDOMONAS CETRIMIDE AGAR (ISO 8360-1)
6100415	PSEUDOMONAS CETRIMIDE AGAR
610042	SS AGAR (MODIFIED)
6100425	SS AGAR (MODIFIED)
610043	SCHAEDLER AGAR BASE
610044	PURPLE LACTOSE AGAR
610046	SIMMONS CITRATE AGAR
610047	MONSUR AGAR
610048	AEROMONAS AGAR BASE
610049	LEGIONELLA BCYE AGAR BASE (ISO 11731)
610050	Fluid Thioglycollate Medium
6100505	Fluid Thioglycollate Medium
610051	TODD HEWITT BROTH
6100515	TODD HEWITT BROTH
610052	TRYPTIC SOY AGAR
6100525	TRYPTIC SOY AGAR (Harm.EP) 5 KG
610053	TRYPTIC SOY BROTH
6100535	TRYPTIC SOY BROTH
610055	T.S.I. AGAR USP
610056	CLOSTRIDIUM BROTH
6100565	CLOSTRIDIUM BROTH
610057	MAC CONKEY AGAR No.2
6100575	MAC CONKEY AGAR No.2 5 KG
610060	X.L.D. AGAR (ISO 6579)
6100605	X.L.D. AGAR
610061	TRICHOMONAS BROTH
610065	GSB AGAR BASE (ISLAM)
610070	YEAST GLUCOSE CHLORAMPHENICOL AGAR
6100705	YEAST GLUCOSE CHLORAMPHENICOL AGAR 5 Kg
610071	PSEUDOMONAS AGAR BASE

610072	CZAPEK DOX BROTH
610074	TRYPTONE SULFITE NEOMYCIN AGAR
610075	PHENYLALANINE MALONATE BROTH
610079	BRUCELLA AGAR BASE
610080	WORT BROTH W/O NaCl
610092	XLT 4 AGAR
610095	CZAPEK DOX AGAR
610096	REINFORCED CLOSTRIDIAL AGAR
610097	STAPHYLOCOCCUS BROTH
610098	ALKALINE PEPTONE WATER
610101	MALT AGAR
610103	SABOURAUD AGAR
6101035	SABOURAUD AGAR
610104	SABOURAUD BROTH
610107	UREA AGAR BASE (ISO 6785)
610108	MAC CONKEY SORBITOL AGAR
610109	P.P.L.O. BROTH
610110	MUELLER HINTON AGAR MODIFIED
610111	YERSINIA SELECTIVE AGAR BASE
610112	CLED ANDRADE AGAR
610113	COLUMBIA CNA AGAR BASE
610114	BACILLUS CEREUS AGAR BASE (MOSSEL) ISO 7932
610115	CLOSTRIDIUM DIFFICILE AGAR BASE
610117	TRYPTONE YEAST AGAR
610118	ANDRADE LACTOSE PEPTONE WATER
610123	CORN MEAL AGAR
610125	LEGIONELLA CYE AGAR BASE
610128	MAC CONKEY AGAR w/o BILE SALT
610130	CAMPYLOBACTER BLOOD FREE MEDIUM BASE
610131	CAMPYLOBACTER ENRICHMENT BROTH BASE
610132	MOTILITY TEST AGAR
610134	SLANETZ BARTLEY AGAR BASE ISO 7899-2
610135	BIGGY (NICKERSON) AGAR
610136	BACILLUS CEREUS AGAR BASE (PEMBA)
610137	SCHAEDLER BROTH
610140	E.M.B. AGAR w LACTOSE + SUCROSE
610143	LIVER BROTH
610144	MRS BROTH w/o GLUCOSE
610145	SELENITE BROTH
6101455	SELENITE BROTH
610146	SABOURAUD MALTOSE AGAR
610147	SLANETZ AND BARTLEY AGAR + TTC
6101475	SLANETZ AND BARTLEY AGAR + TTC
610148	SPS AGAR
610151	BILE AESCULIN BROTH
610152	AMIES TRANSPORT MEDIUM + CHARC.
6101525	AMIES TRANSPORT MEDIUM + CHARC.
610153	AZIDE BLOOD AGAR BASE
610155	AZIDE VIOLET BLOOD AGAR BASE
610157	BIOTONE AGAR
610158	BIOTONE BROTH
610159	CPLM SELECTIVE WITH CAF
610160	DERMATOPHYTE (D.T.M.) AGAR
610161	DEXTROSE BROTH
610163	G.N. HAJNA BROTH
610164	HERELLEA AGAR
6101645	HERELLEA AGAR
610165	KOSER CITRATE MEDIUM
610168	LISTERIA PALCAM AGAR
610169	I.U.T.M. MEDIUM
610170	MAC CONKEY MMG AGAR
6101705	MAC CONKEY MMG AGAR
610172	MALONATE BROTH
610174	PHENOL RED BROTH BASE
610175	RAPPAPORT VASSILIADIS BROTH (ISO 6785-6579)
610176	ROGOSA AGAR
610177	ROGOSA BROTH
610179	SABOURAUD CAF AGAR + ACTIDIONE
610180	S.F. BROTH
610181	S.I.M. MEDIUM
610182	STUART TRANSPORT MEDIUM
610183	TETRATHIONATE BROTH BASE
610185	TRYPTIC (CTA) MEDIUM
610186	VOGEL JOHNSON AGAR
610188	BLOOD AGAR BASE N. 2
610191	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
6101915	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
610193	TRYPTOSE AGAR
610195	MAC CONKEY AGAR w/o CRYSTAL VIOLET
610196	TRYPTIC BILE AGAR
610197	TRYPTOFAN BROTH
610200	CAMPYLOBACTER KARMALI AGAR BASE
610203	SABOURAUD CAF AGAR
6102035	SABOURAUD CAF AGAR 5 KG
610205	DNase TEST AGAR
610206	TRYPTONE WATER (ISO/DIS 3811)
610207	CLOSTRIDIUM PERFRIGENS AGAR BASE
610210	BILE AESCULIN AGAR
610211	KLIGLER IRON AGAR MOD.
610214	MIDDLEBROOK 7H9 BROTH BASE
610217	NUTRIENT BROTH N.2
610218	Mueller Hinton II Broth
610221	ANTIBIOTIC TEST MEDIUM
610222	CLOSTRIDIUM BROTH w/o AGAR
6102225	CLOSTRIDIUM BROTH w/o AGAR
610223	MAC CONKEY AGAR w/o Salt
610227	PHENOL RED AGAR BASE
610229	ANTIBIOTIC MEDIUM E
610230	OXIDATIVE/FERMENTATIVE MEDIUM
610233	TRYPTOSE BROTH
610235	MANNITOL MOTILITY TEST MEDIUM
610236	MOTILITY INDOLE UREA AGAR (M.I.U.)
610241	TRYPTONE SOYA YEAST EXTRACT BROTH
610245	LB AGAR
610301	BISMUTH SULPHITE AGAR
610303	Lysine Decarboxylase Broth
610304	OF BASAL MEDIUM
610305	ORNITHINE DECARBOXYLASE BROTH
610306	ARGININE DECARBOXYLASE BROTH
610308	PHENOL RED AGAR BASE
610309	PSEUDOMONAS AGAR F
610310	PSEUDOMONAS AGAR P
610311	UREA BROTH
610315	ANTIBIOTIC AGAR N.11
610319	PFIZER SELECTIVE ENTEROCOCCUS AGAR
610322	NITRATE BROTH
610331	DIAGNOSTIC SENSITIVITY TEST AGAR (D.S.T.)
610339	T.S.I. AGAR acc.EP
610341	EMGON BROTH
610343	MANNITOL SALT BROTH

610363	Yeast Extract Sodium Lactate medium
610364	Tryptose Phosphate Broth
6103645	Tryptose Phosphate Broth
610372	Cooked Meat Medium
610492	POLYPEPTONE
610495	BRAIN HEART INFUSION
6104955	BRAIN HEART INFUSION
610496	ACID HYDROLISATE OF CASEIN
610497	BEEF EXTRACT
6104975	BEEF EXTRACT
610498	LACTOSE
6104985	LACTOSE
610506	CYSTINE HEART AGAR
610611	CHROMATIC™ SALMONELLA
610612	CHROMATIC™ DETECTION
6106125	CHROMATIC™ DETECTION
610613	CHROMATIC™ CANDIDA
610614	Chromatic™ E.coli O157
610615	CHROMATIC™ MRSA
610616	CHROMATIC™ STAPH AUREUS
610617	CHROMATIC™ STREP B
610625	SABOURAUD CAF (50 mg/L) AGAR
610627	MUELLER HINTON II AGAR
6106275	MUELLER HINTON II AGAR
610629	CHROMATIC™ ESBL
611000	SODIUM CHLORIDE
611001	AGAR
6110015	AGAR
611002	GELATIN BACTERIOLOGICAL
6110025	GELATIN BACTERIOLOGICAL
611003	SODIUM SELENITE
6110035	SODIUM SELENITE
611004	TRYPTONE
6110045	TRYPTONE
611005	YEAST EXTRACT
6110055	YEAST EXTRACT
611006	MALT EXTRACT
6110065	MALT EXTRACT
611007	CAMPYLOBACTER AGAR BASE
611008	TRYPTOSE
6110085	TRYPTOSE
611009	GLUCOSIO
611010	T.C.B.S. AGAR
611015	SIERRA LIPOLYTIC AGAR
611016	YEAST EXTRACT AGAR (ISO 6222)
611021	HEART INFUSION BROTH
6110215	HEART INFUSION BROTH
611022	MIDDLEBROOK 7H10 AGAR BASE
611203	SABOURAUD CAF (1g/l) AGAR
611210	WURTZ LACTOSE AGAR
611265	ISOSENSITEST AGAR
611366	STAPHYLOCOCCUS 110 AGAR
611367	BILE BACTERIOLOGICAL
611401	IRON SULPHITE AGAR
611402	CARY BLAIR TRANSPORT MEDIUM
611502	CASEIN PEPTONE
611601	GLUCOSE
6116015	GLUCOSE
611618	CHROMATIC™ MH
611619	CHROMATIC™ CRE AGAR BASE

611701	PEPTONE BACTERIOLOGICAL
6117015	PEPTONE BACTERIOLOGICAL
611801	SUCROSE
6118015	SUCROSE
611901	BILE SALT N.3
6119015	BILE SALT N.3
612001	LIVER EXTRACT
6120015	LIVER EXTRACT
612101	PEPTONE MYCOLOGICAL
6121015	PEPTONE MYCOLOGICAL
612201	PROTEOSE PEPTONE
6122015	PROTEOSE PEPTONE
612202	STREPTOCOCCUS SELECTIVE AGAR
612203	STREPTOCOCCUS BROTH
612501	SOY PEPTONE
6125015	SOY PEPTONE
620001	BILE AESCULIN AZIDE AGAR
620002	DEXTROSE AGAR
620005	BLOOD AGAR BASE
620006	BORDET GENGOU AGAR BASE
620007	BRAIN HEART INFUSION AGAR
620008	BRAIN HEART INFUSION BROTH
620009	BRILLIANT GREEN AGAR
620012	CLED AGAR
620013	COLUMBIA AGAR BASE
620014	DESOXYCHOLATE AGAR
620015	DESOXYCHOLATE CITRATE AGAR
620016	DRIGALSKY LACTOSE AGAR
620019	E.M.B. LEVINE AGAR
620021	HEKTOEN ENTERIC AGAR
620022	G.C. MEDIUM
620023	KLIGLER IRON AGAR
620024	M.R.S. AGAR (ISO/FDIS 15214)
620025	M.R.S. BROTH (ISO/FDIS 15214)
620026	LOWENSTEIN JENSEN MEDIUM
620027	LYSINE IRON AGAR
620028	MAC CONKEY AGAR
620029	MANNITOL SALT AGAR
620032	MR-VP BROTH
620033	MUELLER HINTON AGAR
620034	MUELLER HINTON BROTH
620035	MULLER KAUFFMANN BROTH
620036	NUTRIENT AGAR
620037	NUTRIENT BROTH
620038	PEPTONE WATER
620039	PHENYLALANINE AGAR
620041	PSEUDOMONAS CETRIMIDE AGAR (ISO 8360-1)
620042	SS AGAR (MODIFIED)
620043	SCHAEDLER AGAR BASE
620044	PURPLE LACTOSE AGAR
620046	SIMMONS CITRATE AGAR
620047	MONSUR AGAR
620048	AEROMONAS AGAR BASE
620049	LEGIONELLA BCYE AGAR BASE (ISO 11731)
620050	Fluid Thioglycollate Medium
620051	TODD HEWITT BROTH
620052	TRYPTIC SOY AGAR
620053	TRYPTIC SOY BROTH
620055	T.S.I. AGAR USP
620056	CLOSTRIDIUM BROTH

620057	MAC CONKEY AGAR No.2
620060	X.L.D. AGAR (ISO 6579)
620061	TRICHOMONAS BROTH
620065	GSB AGAR BASE (ISLAM)
620070	YEAST GLUCOSE CHLORAMPHENICOL AGAR
620071	PSEUDOMONAS AGAR BASE
620072	CZAPEK DOX BROTH
620074	TRYPTONE SULFITE NEOMYCIN AGAR
620075	PHENYLALANINE MALONATE BROTH
620079	BRUCELLA AGAR BASE
620092	XLT 4 AGAR
620095	CZAPEK DOX AGAR
620096	REINFORCED CLOSTRIDIAL AGAR
620097	STAPHYLOCOCCUS BROTH
620098	ALKALINE PEPTONE WATER
620101	MALT AGAR
620103	SABOURAUD AGAR
620104	SABOURAUD BROTH
620107	UREA AGAR BASE (ISO 6785)
620108	MAC CONKEY SORBITOL AGAR
620109	P.P.L.O. BROTH
620110	MUELLER HINTON AGAR MODIFIED
620111	YERSINIA SELECTIVE AGAR BASE
620112	CLED ANDRADE AGAR
620113	COLUMBIA CNA AGAR BASE
620114	BACILLUS CEREUS AGAR BASE (MOSSEL) ISO 7932
620115	CLOSTRIDIUM DIFFICILE AGAR BASE
620117	TRYPTONE YEAST AGAR
620118	ANDRADE LACTOSE PEPTONE WATER
620122	MIDDLEBROOK 7H10 AGAR BASE
620123	CORN MEAL AGAR
620125	LEGIONELLA CYE AGAR BASE
620130	CAMPYLOBACTER BLOOD FREE MEDIUM BASE
620131	CAMPYLOBACTER ENRICHMENT BROTH BASE
620132	MOTILITY TEST AGAR
620134	SLANETZ BARTLEY AGAR BASE ISO 7899-2
620135	BIGGY (NICKERSON) AGAR
620136	BACILLUS CEREUS AGAR BASE (PEMBA)
620137	SCHAEDLER BROTH
620140	E.M.B. AGAR w LACTOSE + SUCROSE
620143	LIVER BROTH
620144	MRS BROTH w/o GLUCOSE
620145	SELENITE BROTH
620146	SABOURAUD MALTOSE AGAR
620147	SLANETZ AND BARTLEY AGAR + TTC
620148	SPS AGAR
620151	BILE AESCULIN BROTH
620152	AMIES TRANSPORT MEDIUM + CHARC.
620153	AZIDE BLOOD AGAR BASE
620155	AZIDE VIOLET BLOOD AGAR BASE
620157	BIOTONE AGAR
620158	BIOTONE BROTH
620159	CPLM SELECTIVE WITHCAF
620160	DERMATOPHYTE (D.T.M.) AGAR
620161	DEXTROSE BROTH
620163	G.N. HAJNA BROTH
620164	HERELLEA AGAR
620165	KOSER CITRATE BROTH
620168	LISTERIA PALCAM AGAR
620169	I.U.T.M. MEDIUM
620170	MAC CONKEY MMG AGAR
620172	MALONATE BROTH
620174	PHENOL RED BROTH BASE
620175	RAPPAPORT VASSILIADIS BROTH
620176	ROGOSA AGAR
620177	ROGOSA BROTH
620179	SABOURAUD CAF AGAR + ACTIDIONE
620180	S.F. BROTH
620181	S.I.M. MEDIUM
620182	STUART TRANSPORT MEDIUM
620183	TETRATHIONATE BROTH BASE
620185	TRYPTIC (CTA) MEDIUM
620186	VOGEL JOHNSON AGAR
620188	BLOOD AGAR BASE N. 2
620191	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
620193	TRYPTOSE AGAR
620195	MAC CONKEY AGSAR w/o CRYSTAL VIOLET
620196	TRYPTIC BILE AGAR
620197	TRYPTOFAN BROTH
620200	CAMPYLOBACTER KARMALI AGAR BASE
620203	SABOURAUD CAF AGAR
620205	DNase TEST AGAR
620206	TRYPTONE WATER (ISO/DIS 3811)
620207	CLOSTRIDIUM PERFRIGENS AGAR BASE
620210	BILE AESCULIN AGAR
620211	KLIGLER IRON AGAR MOD.
620214	MIDDLEBROOK 7H9 BROTH BASE
620217	NUTRIENT BROTH N.2
620218	Mueller Hinton II Broth
620227	PHENOL RED AGAR BASE
620229	ANTIBIOTIC MEDIUM E
620233	TRYPTOSE BROTH
620235	MANNITOL MOTILITY TEST MEDIUM
620241	TRYPTONE SOYA YEAST EXTRACT BROTH
620303	Lysine Decarboxylase Broth
620309	PSEUDOMONAS AGAR F
620311	UREA BROTH
620495	BRAIN HEART INFUSION
620496	ACID HYDROLISATE OF CASEIN
620497	BEEF EXTRACT
620498	LACTOSE
620611	CHROMATIC™ SALMONELLA
620612	CHROMATIC™ DETECTION
620613	CHROMATIC™ CANDIDA
620614	Chromatic™ E.coli O157
620615	CHROMATIC™ MRSA
620616	CHROMATIC™ STAPH AUREUS
620617	CHROMATIC™ STREP B
620627	MUELLER HINTON II AGAR
620629	CHROMATIC™ ESBL
621000	SODIUM CHLORIDE
621001	AGAR
621003	SODIUM SELENITE
621004	TRYPTONE
621005	YEAST EXTRACT
621006	MALT EXTRACT
621007	CAMPYLOBACTER AGAR BASE
621010	TCBS AGAR
621015	SIERRA LIPOLYTIC AGAR
621016	YEAST EXTRACT AGAR (ISO 6222)

621021	HEART INFUSION BROTH
621022	MIDDLEBROOK 7H10 AGAR BASE
621210	WURTZ LACTOSE AGAR
621265	ISOSENSITEST AGAR
621367	BILE BACTERIOLOGICAL
621401	IRON SULPHITE AGAR
621402	CARY BLAIR TRANSPORT MEDIUM
621601	GLUCOSE
621618	CHROMATIC™ MH
621619	CHROMATIC™ CRE AGAR BASE
621701	PEPTONE BACTERIOLOGICAL
622202	STREPTOCOCCUS SELECTIVE AGAR
630026	LOWENSTEIN JENSEN MEDIUM w GLYCEROL 1 litre
71618	ENTEROSYSTEM 18R 20 Tests
71630	STAF SYSTEM 18 R 20 Tests
71670	COPRO SYSTEM 40 Tests
71675	COPRO SYSTEM Plus 20 Tests
71678	PATHOGENIC SYSTEM DOUBLE 40 Tests
71679	PATHOGENIC SYSTEM 20 Tests
71681	PATHOGENIC SYSTEM AST
71714	INTEGRAL SYSTEM ENTEROBATTERI 20 Tests
71718	INTEGRAL SYSTEM STAFILOCOCCHI 20 Tests
71720	INTEGRAL SYSTEM STREPTOCOCCHI 20 Tests
71724	INTEGRAL SYSTEM GARDNERELLA 20 TESTS
71822	INTEGRAL SYSTEM YEASTS Plus 20 Tests
72560	STREPTO SYSTEM 12 R 40 Tests
72592	MYCOPLASMA SYSTEM Plus 20 Tests
74156	A.F. GENITAL SYSTEM 20 Tests
74160	URIN SYSTEM Plus 20 Tests
74161	URIN SYSTEM Chrom 20 Tests
76010	Sensi Test gram-negative 20 Tests
76020	Sensi Test gram-positive 20 Tests
76031	SensiQuattro Gram-negative 20 Tests
76032	SensiQuattro Gram-positive 20 Tests
76033	SensiQuattro Candida EU 20 Tests
78618	ENTERO PLURI TEST 10 Tests
78619	ENTERO PLURI TEST 25 Tests
78620	OXI/FERM PLURI TEST 10 Tests
78621	OXI/FERM PLURI TEST 25 Tests
79010	Sensi Test gram-negative 4 Tests
79020	Sensi Test gram-positive 4 Tests
79031	SensiQuattro Gram-negative 4 Tests
79032	SensiQuattro Gram-positive 4 Tests
79033	SensiQuattro Candida EU 4 Tests
79156	A.F. GENITAL SYSTEM 4 Tests
79160	URIN SYSTEM Plus 4 Tests
79161	URIN SYSTEM Chrom 4 Tests
79560	STREPTO SYSTEM 12 R 8 Tests
79592	MYCOPLASMA SYSTEM Plus 4 Tests
79618	ENTEROSYSTEM 18R 4 Tests
79630	STAF SYSTEM 18 R 4 Tests
79670	COPRO SYSTEM 8 Tests
79675	COPRO SYSTEM Plus 4 Tests
79678	PATHOGENIC SYSTEM DOUBLE 8 Tests
79679	PATHOGENIC SYSTEM 4 Tests
79681	PATHOGENIC SYSTEM AST
79714	INTEGRAL SYSTEM ENTEROBATTERI 4 Tests
79718	INTEGRAL SYSTEM STAFILOCOCCHI 4 Tests
79720	INTEGRAL SYSTEM STREPTOCOCCHI 4 Tests
79724	INTEGRAL SYSTEM GARDNERELLA 4 Tests
79822	INTEGRAL SYSTEM YEASTS Plus 4 Tests
80009	IODINE MKTT SOLUTION 10 x 10 ml
80010	XLT 4 supplement 2 x 50 ml
80021	GLYCEROL supplement 4 x 50 ml
80022	POTASSIUM TELLURITE 1% suppl. 5 x 10 ml
80031	TWEEN 80 supplement 2 x 50 ml
80040	CHROMATIC™ SALMONELLA Supplement 2x50 ml
80047	MULLER KAUFFMANN 3X50 ml (Iodio/B.G.0.1%)
80053	VITAMIN K 1% supplement 5 x 5 ml
80056	LEGIONELLA growth supplement 10 vials
80057	H2O2 REAGENT 1 x 10 ml
80060	DECONTAM-KIT
80110	UREA 40% 6X100 ml
80219	EGG YOLK emulsion 4 x 50 ml
80252	ENTEROSYSTEM 18R REAGENT 100/200 Tests
80253	COPRO SYSTEM REAGENTS (antisera)
80257	LISTERIA SYSTEM 18R -REAG 100/200 Tests
80258	AF GENITAL SYSTEM REAGENT
80260	IDENTIF. SYSTEM-REAGENT 100/200 Tests
80271	KOVAC'S REAGENT 4x25 ml
80272	FERRIC CHLORIDE 10% 2x 25 ml
80273	NINHYDRIN 7% 10 ml
80275	MIF COLOR KIT 50 Tests
80276	ZIEHL-NEELSEN 3 x 250 ml
80277	METHYLENE BLUE Solution 250 ml
80279	VASELINE OIL 4 x 50 ml
80280	V.P. TEST-Reagent 10x10ml
80281	V.P. TEST EP 10 x 10 mL
80282	Kit May-Grünwald Giemsa
80290	SAFRANIN SOLUTION 1000 ml
80291	POTASSIUM TELLURITE 3.5% suppl.5x10 ml
80292	UREA 40 % supplement 10 x 5 ml
80293	GRAM COLOR KIT 4 x 250 ml
80294	KIT COLOR ALBERT 2 x 250 ml
80295	DECOLOURIZING SOLUTION 1000 ml
80296	LUGOL PVP SOLUTION 1000 ML
80297	SAFRANIN SOLUTION 500 ml
80298	LUGOL PVP SOLUTION 250 ml
80299	CRYSTAL VIOLET SOLUTION 1000 ml
80300	TTC 1% supplement 5 x 10 ml
80350	ANTIBIOTIC TEST
80351	RAPID ANTIBIOTIC TEST 50 Tests
80380	KINYOUN COLOR KIT 2 x 250 ml
80390	FIXUR 1
80409	IODINE SOLUTION 10 x 10 ml
80410	XLT 4 SUPPLEMENT 4 x 50 ml
80422	POTASSIUM TELLURITE 1% Supplement 10 x 10 ml
80430	TTC 1% supplement 10 x 10 ml
80431	TWEEN 80 Supplement 4 x 50 ml
80453	VITAMIN K 1% SUPPLEMENT 10 x 5 ml
80491	POTASSIUM TELLURITE 3,5% Supplement 10 x 10
81001	AMPICILLIN supplement 10 vials
81002	LEGIONELLA (BMPA) supplement 10 vials
81003	BRUCELLA supplement 10 vials
81004	CAMPYLOBACTER Preston supplem 10 vials
81006	CN (Pseudomonas) supplement 10 vials
81007	CLOSTRIDIUM difficile suppleme 10 vials
81008	LEGIONELLA (GVPC) supplement 10 vials
81009	IODINE solution 5 x 10 ml
81011	CLOSTRIDIUM perfrigens (T.S.C.) sup.10 v.

81012	LCAT supplement 10 vials
81013	BORDETELLA supplement 10 vials
81014	HAEMOPHILUS supplement 10 vials
81015	CAMPYLOBACTER Butzler supplement 10 vials
81016	BACILLUS Cereus Supplement 10 Vials
81017	CHLORAMPHENICOL supplement 10 vials
81019	LEGIONELLA (MWY) supplement 10 vials
81020	MMG Supplement 10 vials
81022	V.C.N. supplement 10 vials
81023	VITALEX growth supplement 10 vials
81024	V.C.N.T. supplement 10 vials
81025	DERMATOPHYTE supplement 10 vials
81026	LISTERIA PALCAM supplement 10 vials
81032	ONPG 1.5% Supplement 10 vials
81033	GENTAMYCIN supplement 10 vials
81035	MIDDLEBROOK 7H 10 supplement 4 x 50 ml
81036	CAMPYLOBACTER KARMALI Supplement 10 vials
81037	CAMPYLOBACTER CCDA supplement 10 vials
81038	CAMPYLOBACTER C.T.V.N. Supplement 10 vials
81039	YERSINIA supplement 10 vials
81040	GARDNERELLA vaginalis Supplement 10vials
81041	V.C.A.T. supplement 10 vials
81042	LISTERIA FRASER supplement (1125mg)10 vials
81048	CNA (Staf/Strep) supplemet 10 vials
81050	CAMPYLOBACTER growth supplement 10 vials
81051	CAMPYLOBACTER Blaser Wang supp 10 vials
81054	SCHAEDLER supplement 10 vials
81055	CAMPYLOBACTER Skirrow supple 10 vials
81056	LEGIONELLA (BCYE) growth suppl.10 vials
81062	VANCOMYCIN Supplement for VRE 10 vials
81077	CAMPYLOBACTER C.T.V.A. Supplement 10 vials
81078	CHROMATIC™ MRSA Supplement
81079	UREA-ARGININE SCREEN
81082	CEFIXIME TELLURITE Supplement
81083	MEROPENEM Supplement
81084	NEOMYCIN Solution
81085	CHROMATIC™ STAPH AUREUS Supplement
81086	VCC MOD SELECTIVE Supplement
81088	CHROMATIC™ CRE Supplement
81089	Chromatic™ ESBL Supplement
81090	CHROMATIC™ ESBL+AmpC Supplement
81091	Legionella BCYE Growth Supplement w/o L-Cysteine
83810	HORSE SERUM 1 x 100 ml
85501	COPRO KIT (SELENITE BROTH)
85502	COPRO KIT 2 (SALMONELLA BROTH)
87001	KOVAC'S Reagent
87002	VP (NaOH) Reagent
87003	CATALASE Reagent
87004	PHENYLALANINE Reagent
87005	OXIDASE Reagent
87006	Vaseline Oil
87007	VP (KOH) Reagent
87008	Lactophenol Cotton Blue Droppers
87101	GRAM COLOR KIT
88001	BETA LACTAMASE TEST 30 Tests
88003	OXIDASE TEST SWABS 30 Tests
88004	OXIDASE TEST DISCS 30 Discs
88005	O.N.P.G. TEST 30 Tests
88006	E.COLI TEST 30 Tests
88007	HIPPURATE TEST 30 Tests

88008	AESCULIN BILE TEST 30 Tests
88009	NITRATI TEST 30 Tests 30 Tests
88010	LISTERIA MONO TEST 20 Tests
88011	UREA RAPID TEST 30 Tests
88013	H2S RAPID TEST 30 Tests
88014	LYSINE DECARBOXYLASE TEST 30 Tests
88015	ORNITHINE DECARBOXYLASE TEST 30 Tests
88016	ARGININE DECARBOXYLASE TEST 30 Tests
88017	INDOLE TEST 30 Tests
88020	S F RAPID TEST 30 Tests
88021	CAMP TEST-S 30 Tests
88023	CATALASI/OXY TEST 30 Tests
88024	UREA / INDOLO TEST 30 Tests
88027	CAMP TEST-R 30 Tests
88028	PEPTIDASE A TEST 30 Tests
88029	OXIDASE TEST STICKS 50 Tests
88030	COAGULASE TEST 40 Tests
88031	GRAM TEST STICK 30 Tests
88032	INDOLO TEST STICK 30 Tests
88033	BETA LACTAMASE STICKS 30 Tests
88034	PEPTIDASE A STICKS 30 Tests
88035	VP TEST KIT
88040	C 390 50 Discs
88041	Brilliant Green 100 µg
88042	CITRATE TEST
88043	O129 Disc 150 µg
88044	O129 Disc 10 µg
88105	O.N.P.G. TEST
88201	GALACTOSE TEST 30 Tests
88202	GLUCOSE TEST 30 Tests
88203	LACTOSE TEST 30 Tests
88204	MALTOSE TEST 30 Tests
88205	RAFFINOSE TEST 30 Tests
88206	SUCROSE TEST 30 Tests
88207	ARABITOL TEST 30 Tests
88208	ADONITOL TEST 30 Tests
88209	ARABINOSE TEST 30 Tests
88210	DULCITOL TEST 30 Tests
88211	INOSITOL TEST 30 Tests
88212	INULIN TEST 30 Tests
88213	LEVULOSE TEST 30 Tests
88214	MANNITOL TEST 30 Tests
88215	MANNOSE TEST 30 Tests
88216	RHAMNOSE TEST 30 Tests
88217	SALICIN TEST 30 Tests
88218	SORBITOL TEST 30 Tests
88219	TREHALOSE TEST 30 Tests
88220	XYLOSE TEST 30 Tests
89021	CultiControl™ Aspergillus brasiliensis ATCC® 16404™
89022	CultiControl™ Bacillus Cereus ATCC® 11778™
89023	CultiControl™ Bacillus subtilis ATCC® 6633™
89024	CultiControl™ Candida albicans ATCC® 10231™
89025	CultiControl™ Enterococcus faecalis ATCC® 19433™
89026	CultiControl™ Enterococcus faecalis ATCC® 29212™
89027	CultiControl™ Escherichia coli ATCC® 25922™
89028	CultiControl™ Escherichia coli ATCC® 8739™
89029	CultiControl™ Listeria innocua ATCC® 33090™
89030	CultiControl™ Listeria ivanovii ATCC® 19119™
89031	CultiControl™ Listeria monocytogenes ATCC® 19111™
89032	CultiControl™ Proteus mirabilis ATCC® 25933™

89033	CultiControl™ Pseudomonas aeruginosa ATCC® 27853™
89034	CultiControl™ Pseudomonas aeruginosa ATCC® 9027™
89035	CultiControl™ Rhodococcus equi ATCC® 6939™
89036	CultiControl™ Saccharomyces cerevisiae ATCC® 9763™
89037	CultiControl™ Salmonella typhimurium ATCC® 14028™
89038	CultiControl™ Shigella flexneri ATCC® 12022™
89039	CultiControl™ Staphylococcus aureus NCTC 12493
89040	CultiControl™ Staphylococcus aureus ATCC® 25923™
89041	CultiControl™ Staphylococcus aureus ATCC® 29213™
89042	CultiControl™ Staphylococcus aureus ATCC® 33862™
89043	CultiControl™ Staphylococcus aureus ATCC® 43300™
89044	CultiControl™ Staphylococcus aureus ATCC® 6538™
89045	CultiControl™ Staphylococcus epidermidis ATCC® 12228™
89046	CultiControl™ Streptococcus agalactiae ATCC® 13813™
89047	CultiControl™ Streptococcus pneumoniae ATCC® 49619™
89048	CultiControl™ Streptococcus pyogenes ATCC® 19615™
89049	CultiControl™ Proteus mirabilis ATCC® 12453™
89050	CultiControl™ Yersinia enterocolitica ATCC® 9610™
89051	CultiControl™ Listeria monocytogenes ATCC® 19115™
89052	CultiControl™ Legionella pneumophila subsp. pneumophila ATCC® 33152™
89053	CultiControl™ Clostridium perfringens ATCC® 13124™
89054	CultiControl™ Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 13311™
89055	CultiControl™ Lactobacillus paracasei subsp. paracasei ATCC ® BAA-52™
89056	CultiControl™ Vibrio parahaemolyticus ATCC ® 17802™
89057	CultiControl™ Aspergillus fumigatus ATCC ® 204305™
89058	CultiControl™ Shigella sonnei ATCC ® 25931™
89059	CultiControl™ Clostridium sordellii ATCC ® 9714™
89060	CultiControl™ Listeria monocytogenes ATCC ® 7644™
89061	CultiControl™ Streptococcus bovis ATCC ® 33317™
89062	CultiControl™ Streptococcus mutans ATCC ® 25175™
89063	CultiControl™ Streptococcus pneumoniae ATCC ® 27336™
89064	CultiControl™ Streptococcus sanguinis ATCC ® 10556™
89065	CultiControl™ Enterobacter cloacae subsp. cloacae ATCC ® BAA-1143™
89066	CultiControl™ Enterococcus faecalis ATCC ® 49532™
89067	CultiControl™ Enterococcus faecalis ATCC ® 49533™
89068	CultiControl™ Escherichia coli NCTC 11954™
89069	CultiControl™ Klebsiella pneumoniae ATCC ® BAA-2146™
89070	CultiControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC ® 700603™
89071	CultiControl™ Candida parapsilosis ATCC ® 22019™
89072	CultiControl™ Candida albicans ATCC ® 90028™
89073	CultiControl™ Issatchenkia orientalis ATCC ® 6258™
89074	CultiControl™ Neisseria gonorrhoeae ATCC ® 19424™
89075	CultiControl™ Neisseria gonorrhoeae ATCC ® 31426™
89076	CultiControl™ Haemophilus influenzae ATCC® 49766™
89077	CultiControl™ Haemophilus influenzae ATCC® 49247™
89078	CultiControl™ Bacteroides fragilis ATCC® 25285™
89079	CultiControl™ Bacteroides thetaiotaomicron ATCC® 29741™
89080	CultiControl™ Lactobacillus acidophilus ATCC ® 4356™
89081	CultiControl™ Lactobacillus leichmannii ATCC ® 4797™
89082	CultiControl™ Lactococcus lactis ATCC ® 19435™
89083	CultiControl™ Proteus mirabilis ATCC ® 29906™
89084	CultiControl™ Salmonella enterica subsp. enterica serovar Enteritidis ATCC ® 13076™
89085	CultiControl™ Listeria monocytogenes ATCC ® 13932™
89086	CultiControl™ Campylobacter jejuni ATCC ® 33291™
89087	CultiControl™ Klebsiella pneumoniae ATCC ® BAA-1706™
89088	CultiControl™ Klebsiella pneumoniae ATCC ® BAA-1705™
89089	CultiControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC ® 13883™
89090	CultiControl™ Clostridium difficile ATCC ® 9689™
89091	CultiControl™ Aggregatibacter aphrophilus ATCC ® 7901™
89092	CultiControl™ Staphylococcus aureus subsp. aureus ATCC® 700698™
89093	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® 700699™
89094	CultiControl™ Plesiomonas shigelloides ATCC ® 14029™
89095	CultiControl™ Clostridium sporogenes ATCC ® 19404™
89096	CultiControl™ Micrococcus luteus ATCC ® 10240™
89097	CultiControl™ Candida tropicalis ATCC ® 750™
89098	CultiControl™ Candida krusei ATCC ® 14243™
89099	CultiControl™ Gardnerella vaginalis ATCC ® 14018™
89100	CultiControl™ Lactobacillus fermentum ATCC ® 9338™
89101	CultiControl™ Listeria grayi ATCC ® 25401™
89102	CultiControl™ Micrococcus luteus ATCC ® 4698™
89103	CultiControl™ Moraxella (Branhamella) catarrhalis ATCC ® 25238™
89104	CultiControl™ Neisseria gonorrhoeae ATCC ® 49226™
89105	CultiControl™ Proteus mirabilis ATCC ® 35659™
89106	CultiControl™ Proteus mirabilis ATCC ® 43071™
89107	CultiControl™ Proteus vulgaris ATCC ® 6380™
89108	CultiControl™ Pseudomonas aeruginosa ATCC ® 10145™
89109	CultiControl™ Pseudomonas aeruginosa ATCC ® 15442™
89110	CultiControl™ Pseudomonas fluorescens ATCC ® 13525™
89111	CultiControl™ Bacteroides ovatus ATCC ® 8483™
89112	CultiControl™ Clostridium histolyticum ATCC ® 19401™
89113	CultiControl™ Bacteroides fragilis ATCC ® 23745™
89114	CultiControl™ Actinomyces odontolyticus ATCC ® 17929™
89115	CultiControl™ Enterococcus faecalis ATCC ® 33186™
89116	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® 33591™
89117	CultiControl™ Enterococcus faecium ATCC ® 51559™
89118	CultiControl™ Fusobacterium nucleatum ATCC ® 25586™
89119	CultiControl™ Aeromonas hydrophila ATCC ® 7966™
89120	CultiControl™ Haemophilus influenzae ATCC ® 10211™
89121	CultiControl™ Serratia marcescens ATCC ® 8100™
89122	CultiControl™ Neisseria gonorrhoeae ATCC ® 49981™
89123	CultiControl™ Haemophilus haemolyticus ATCC ® 33390™
89124	CultiControl™ Haemophilus influenzae ATCC ® 33533™
89125	CultiControl™ Providencia stuartii ATCC ® 33672™
89126	CultiControl™ Staphylococcus haemolyticus ATCC ® 29970™
89127	CultiControl™ Streptococcus anginosus ATCC ® 33397™
89128	CultiControl™ Streptococcus dysgalactiae subsp.equisimilis ATCC ® 12388™
89129	CultiControl™ Streptococcus mitis ATCC ® 6249™
89130	CultiControl™ Streptococcus pyogenes ATCC ® 49399™
89131	CultiControl™ Streptococcus salivarius ATCC® 13419™
89132	CultiControl™ Salmonella enterica subsp. enterica serovar Abony NCTC 6017
89133	CultiControl™ Staphylococcus xylosus ATCC ® 29971™
89135	CultiControl™ Propionibacterium acnes ATCC® 11827™
89136	CultiControl™ Haemophilus influenzae NCTC 8468
89137	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® 19095™
89138	CultiControl™ Cronobacter sakazakii ATCC ® 29544™
89139	CultiControl™ Bordetella bronchiseptica ATCC ® 4617™
89140	CultiControl™ Trichophyton mentagrophytes ATCC ® 9533™

89141	CultiControl™ Acinetobacter baumannii ATCC ® BAA-747™
89144	CultiControl™ Vibrio alginolyticus ATCC ® 17749™
89145	CultiControl™ Campylobacter jejuni subsp. jejuni ATCC ® 33560™
89146	CultiControl™ Citrobacter freundii ATCC ® 43864™
89147	CultiControl™ Burkholderia cepacia ATCC ® 25416™
89148	CultiControl™ Listeria monocytogenes ATCC ® 35152™
89149	CultiControl™ Stenotrophomonas maltophilia ATCC® 13637™
89151	CultiControl™ Legionella pneumophila subsp. fraseri ATCC ® 33156™
89152	CultiControl™ Enterococcus faecium ATCC ® 6057™
89154	CultiControl™ Salmonella enterica subsp. arizonae ATCC ® 13314™
89156	CultiControl™ Enterobacter aerogenes ATCC ® 13048™
89160	CultiControl™ Haemophilus influenzae ATCC ® 19418™
89163	CultiControl™ Escherichia coli ATCC ® 35218™
89164	CultiControl™ Neisseria meningitidis ATCC ® 13090™
89165	CultiControl™ Peptostreptococcus anaerobius ATCC ® 27337™
89170	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® BAA-44™
89171	CultiControl™ Enterococcus faecium ATCC ® 19434™
89172	CultiControl™ Enterococcus faecium ATCC ® BAA-2319™
89173	CultiControl™ Enterococcus faecalis ATCC ® 51299™
89174	CultiControl™ Acinetobacter baumannii ATCC ® 19606™
89175	CultiControl™ Streptococcus pneumoniae ATCC ® 700671™
89176	CultiControl™ Haemophilus influenzae ATCC ® 33391™
89177	CultiControl™ Candida albicans ATCC ® 18804™
89178	CultiControl™ Candida albicans ATCC ® 64124™
9001	NALIDIXIC ACID NA 30 µg 250 Discs
9001/1	NALIDIXIC ACID NA 30 µg 50 Discs
9002	Oxolinic acid OA 2 µg 250 Discs
9002/1	Oxolinic acid OA 2 µg 50 Discs
9003	PIPEMIDIC ACID PI 20 µg 250 Discs
9003/1	PIPEMIDIC ACID PI 20 µg 50 Discs
9004	AMIKACIN AK 30 µg 250 Discs
9004/1	AMIKACIN AK 30 µg 50 Discs
9005	AMOXICILLIN AML 30 µg 250 Discs
9005/1	AMOXICILLIN AML 30 µg 50 Discs
9006	AMPICILLIN AMP 10 µg 250 Discs
9006/1	AMPICILLIN AMP 10 µg 50 Discs
9007	AZLOCILLIN AZL 75 µg 250 Discs
9007/1	AZLOCILLIN AZL 75 µg 50 Discs
9008	AZTREONAM ATM 30 µg 250 Discs
9008/1	AZTREONAM ATM 30 µg 50 Discs
9009	CARBENICILLIN CAR 100 µg 250 Discs
9009/1	CARBENICILLIN CAR 100 µg 50 Discs
9010	CEFACLOR CEC 30 µg 250 Discs
9010/1	CEFACLOR CEC 30 µg 50 Discs
9011	CEPHALEXIN CL 30 µg 250 Discs
9011/1	CEPHALEXIN CL 30 µg 50 Discs
9013	CEPHALOTHIN KF 30 µg 250 Discs
9013/1	CEPHALOTHIN KF 30 µg 50 Discs
9014	CEFAMANDOLE MA 30 µg 250 Discs
9014/1	CEFAMANDOLE MA 30 µg 50 Discs
9015	CEFAZOLIN KZ 30 µg 250 Discs
9015/1	CEFAZOLIN KZ 30 µg 50 Discs
9016	CEFOPERAZONE CFP 30 µg 250 Discs
9016/1	CEFOPERAZONE CFP 30 µg 50 Discs
9017	CEFOTAXIME CTX 30 µg 250 Discs
9017/1	CEFOTAXIME CTX 30 µg 50 Discs
9018	CEFOXITIN FOX 30 µg 250 Discs
9018/1	CEFOXITIN FOX 30 µg 50 Discs
9019	CEFTAZIDIME CAZ 30 µg 250 Discs
9019/1	CEFTAZIDIME CAZ 30 µg 50 Discs
9020	CEFTRIAXONE CRO 30 µg 250 Discs
9020/1	CEFTRIAXONE CRO 30 µg 50 Discs
9021	CEFUROXIME CXM 30 µg 250 Discs
9021/1	CEFUROXIME CXM 30 µg 50 Discs
9022	CHLORAMPHENICOL C 30 µg 250 Discs
9022/1	CHLORAMPHENICOL C 30 µg 50 Discs
9023	COLISTIN SULFATE CS 10 µg 250 Discs
9023/1	COLISTIN SULFATE CS 10 µg 50 Discs
9024	ERYTHROMYCIN E 15 µg 250 Discs
9024/1	ERYTHROMYCIN E 15 µg 50 Discs
9025	FOSFOMYCIN FOS 50 µg 250 Discs
9025/1	FOSFOMYCIN FOS 50 µg 50 Discs
9026	GENTAMICIN CN 10 µg 250 Discs
9026/1	GENTAMICIN CN 10 µg 50 Discs
9027	KANAMYCIN K 30 µg 250 Discs
9027/1	KANAMYCIN K 30 µg 50 Discs
9028	LINCOMYCIN MY 2 µg 250 Discs
9028/1	LINCOMYCIN MY 2 µg 50 Discs
9029	METHICILLIN MET 5 µg 250 Discs
9029/1	METHICILLIN MET 5 µg 50 Discs
9030	MINOCYCLINE MN 30 µg 250 Discs
9030/1	MINOCYCLINE MN 30 µg 50 Discs
9031	AMPICILLIN-SULBACTAM AMS 20 µg 250 Discs
9031/1	AMPICILLIN-SULBACTAM AMS 20µg 50 DISCS
9032	NEOMYCIN N 30 µg 250 Discs
9032/1	NEOMYCIN N 30 µg 50 Discs
9033	NETILMICIN NET 30 µg 250 Discs
9033/1	NETILMICIN NET 30 µg 50 Discs
9034	NITROFURANTOIN F 300 µg 250 Discs
9034/1	NITROFURANTOIN F 300 µg 50 Discs
9035	NORFLOXACIN NOR 10µg 250 Discs
9035/1	NORFLOXACIN NOR 10 µg 50 Discs
9036	OXACILLIN OX 1µg 250 Discs
9036/1	OXACILLIN OX 1 µg 50 Discs
9037	PENICILLIN G P 10 IU 250 Discs
9037/1	PENICILLIN G P 10 IU 50 Discs
9038	PIPERACILLIN PRL 100 µg 250 Discs
9038/1	PIPERACILLIN PRL 100 µg 50 Discs
9039	RIFAMPICIN RD 30 µg 250 Discs
9039/1	RIFAMPICIN RD 30 µg 50 Discs
9040	STREPTOMYCIN S 10 µg 250 Discs
9040/1	STREPTOMYCIN S 10 µg 50 Discs
9041	SULFAFURAZOLE SF 300 µg 250 Discs
9041/1	SULFAFURAZOLE SF 300 µg 50 Discs
9042	TRIMETHOPRIM-SULFAMETHOXAZOLE SXT 25 µg 250 Discs
9042/1	TRIMETHOPRIM-SULFAMETHOXAZOLE SXT 25 µg 50 Discs
9043	TETRACYCLINE TE 30 µg 250 Discs
9043/1	TETRACYCLINE TE 30 µg 50 Discs
9044	TOBRAMYCIN TOB 10 µg 250 Discs
9044/1	TOBRAMYCIN TOB 10 µg 50 Discs
9045	VANCOMYCIN VA 30 µg 250 Discs
9045/1	VANCOMYCIN VA 30 µg 50 Discs
9046	SISOMYCIN SIS 30µg 250 Discs
9046/1	SISOMYCIN SIS 30 µg 50 Discs
9047	CLINDAMYCIN CD 2 µg 250 Discs
9047/1	CLINDAMYCIN CD 2 µg 50 Discs

9048	AMOXICILLIN-CLAVULANIC ACID AUG 30 µg 250 Discs
9048/1	AMOXICILLIN-CLAVULANIC ACID AUG 30 µg 50 Discs
9049	FUSIDIC ACID FC 10 µg 250 Discs
9049/1	FUSIDIC ACID FC 10 µg 50 Discs
9050	TEICOPLANIN TEC 30 µg 250 Discs
9050/1	TEICOPLANIN TEC 30 µg 50 Discs
9051	BACITRACIN BA 10 IU 250 Discs
9051/1	BACITRACIN BA 10 IU 50 Discs
9052	CEFADROXIL CDX 30 µg 250 Discs
9052/1	CEFADROXIL CDX 30 µg 50 Discs
9053	CEFSULODIN CSD 30 µg 250 Discs
9053/1	CEFSULODIN CSD 30 µg 50 Discs
9054	CEFTIZOXIME CZX 30 µg 250 Discs
9054/1	CEFTIZOXIME CZX 30 µg 50 Discs
9055	CEPHRADINE CE 30 µg 250 Discs
9055/1	CEPHRADINE CE 30 µg 50 Discs
9056	CIPROFLOXACIN CIP 5 µg 250 Discs
9056/1	CIPROFLOXACIN CIP 5 µg 50 Discs
9057	CINOXACIN CIN 100 µg 250 Discs
9057/1	CINOXACIN CIN 100 µg 50 Discs
9058	CLOXACILLIN CX 5 µg 250 Discs
9058/1	CLOXACILLIN CX 5 µg 50 Discs
9059	DOXYCYCLINE DXT 30 µg 250 Discs
9059/1	DOXYCYCLINE DXT 30 µg 50 Discs
9060	ROXITROMYCIN RXT 15 µg 250 Discs
9060/1	ROXITROMYCIN RXT 15 µg 50 Discs
9061	ERTAPENEM ETP 10 µg 250 Discs
9061/1	ERTAPENEM ETP 10 µg 50 Discs
9062	MEZLOCILLIN MEZ 75 µg 250 Discs
9062/1	MEZLOCILLIN MEZ 75 µg 50 Discs
9063	NOVOBIOCIN NO 30 µg 250 Discs
9063/1	NOVOBIOCIN NO 30 µg 50 Discs
9064	CEFPODOXIME PX 10 ug 250 Discs
9064/1	CEFPODOXIME PX 10 ug 50 Discs
9065	OXYTETRACYCLINE OT 30 µg 250 Discs
9065/1	OXYTETRACYCLINE OT 30 µg 50 Discs
9066	POLYMYXIN B PB 100 IU 250 Discs
9066/1	POLYMYXIN B PB 100 IU 50 Discs
9067	SPECTINOMYCIN SPC 100 µg 250 Discs
9067/1	SPECTINOMYCIN SPC 100 µg 50 Discs
9068	MEROPENEM MRP 10 µg 250 Discs
9068/1	MEROPENEM MRP 10 µg 50 Discs
9069	FLUCONAZOLE FLU 100 µg 250 Discs
9069/1	FLUCONAZOLE FLU 100 µg 50 Discs
9070	TICARCILLIN TC 75 µg 250 Discs
9070/1	TICARCILLIN TC 75 µg 50 Discs
9071	AMPHOTERICIN B AMB 20 µg 250 Discs
9071/1	AMPHOTERICIN B AMB 20 µg 50 Discs
9072	ECONAZOLE ECN 10 µg 250 Discs
9072/1	ECONAZOLE ECN 10 µg 50 Discs
9073	FLUCYTOSINE AFY 1 µg 250 Discs
9073/1	FLUCYTOSINE AFY 1 µg 50 Discs
9074	GRISEOFULVIN AGF 10 µg 250 Discs
9074/1	GRISEOFULVIN AGF 10 µg 50 Discs
9075	KETOCONAZOLE KCA 10 µg 250 Discs
9075/1	KETOCONAZOLE KCA 10 µg 50 Discs
9076	METRONIDAZOLE MTZ 5 µg 250 Discs
9076/1	METRONIDAZOLE MTZ 5 µg 50 Discs
9077	MICONAZOLE MCL 10 µg 250 Discs
9077/1	MICONAZOLE MCL 10 µg 50 Discs

9078	NYSTATIN NY 100 IU 250 Discs
9078/1	NYSTATIN NY 100 IU 50 Discs
9079	IMIPENEM IMI 10 µg 250 Discs
9079/1	IMIPENEM IMI 10 µg 50 Discs
9080	OFLOXACIN OFX 5 µg 250 Discs
9080/1	OFLOXACIN OFX 5 µg 50 Discs
9081	CEFOTETAN CTT 30 µg 250 Discs
9081/1	CEFOTETAN CTT 30 µg 50 Discs
9082	TYLOSIN TY 30 µg 250 Discs
9082/1	TYLOSIN TY 30 µg 50 Discs
9083	TRIMETHOPRIM TM 2.5 µg 250 Discs
9083/1	TRIMETHOPRIM TM 2.5 µg 50 Discs
9084	SULFAMETHOXAZOLE SMX 50 µg 250 Discs
9084/1	SULFAMETHOXAZOLE SMX 50µg 50 Discs
9085	Imipenem + Phenylboronic acid IMI + BO 250 Discs
9085/1	Imipenem + Phenylboronic acid IMI + BO 50 Discs
9086	Imipenem + Cloxacillin IMI + CL 250 Discs
9086/1	Imipenem + Cloxacillin IMI + CL 50 Discs
9087	EDTA ED 250 Discs
9087/1	EDTA ED 50 Discs
9088	SPIRAMYCIN SP 100 µg 250 Discs
9088/1	SPIRAMYCIN SP 100 µg 50 Discs
9089	CEFIXIME CFM 5 µg 250 Discs
9089/1	CEFIXIME CFM 5 µg 50 Discs
9090	Daptomycin DAP 30 µg 250 Discs
9090/1	Daptomycin DAP 30 µg 50 Discs
9091	PEFLOXACIN PEF 5 µg 250 Discs
9091/1	PEFLOXACIN PEF 5 µg 50 Discs
9093	DICLOXACILLIN DCX 1 µg 250 Discs
9093/1	DICLOXACILLIN DCX 1 µg 50 Discs
9094	TIAMULIN T 30 µg 250 Discs
9094/1	TIAMULIN T 30 µg 50 Discs
9095	IMIPENEM/CILASTATIN IMC 20 µg 250 Discs
9095/1	IMIPENEM/CILASTATIN IMC 20 µg 50 Discs
9096	TICARCILLIN-CLAVULINC ACID TTC 85 µg 250 Discs
9096/1	TICARCILLIN-CLAVULINC ACID TTC 85 µg 50 Discs
9097	CLOTRIMAZOLE CLO 50 µg 250 Discs
9097/1	CLOTRIMAZOLE CLO 50 µg 50 Discs
9098	CLARITHROMYCIN CLR 15 µg 250 Discs
9098/1	CLARITHROMYCIN CLR 15 µg 50 Discs
9099	FURAZOLIDON FR 50 µg 250 Discs
9099/1	FURAZOLIDON FR 50 µg 50 Discs
9100	PIPERACILLIN-TAZOBACTAM TZP 110 µg 250 Discs
9100/1	PIPERACILLIN-TAZOBACTAM TZP 110 µg 50 Disc
9101	CEFTIBUTEN CTB 30 µg 250 Discs
9101/1	CEFTIBUTEN CTB 30 µg 50 Discs
9102	LEVOFLOXACIN LEV 5 µg 250 Discs
9102/1	LEVOFLOXACIN LEV 5 µg 50 Discs
9103	MOXIFLOXACIN MOX 5 µg 250 Discs
9103/1	MOXIFLOXACIN MOX 5 µg 50 Discs
9104	CEFEPIME FEP 30 µg 250 Discs
9104/1	CEFEPIME FEP 30 µg 50 Discs
9105	AZITHROMYCIN AZM 15 µg 250 Discs
9105/1	AZITHROMYCIN AZM 15 µg 50 Discs
9106	MYOKAMYCIN MK 15 µg 250 Discs
9106/1	MYOKAMYCIN MK 15 µg 50 Discs
9107	ITRACONAZOLE ITC 50 µg 250 Discs
9107/1	ITRACONAZOLE ITC 50 µg 50 Discs
9108	CEFOPERAZONE CFP 75 µg 250 Discs
9108/1	CEFOPERAZONE CFP 75 µg 50 Discs

9109	FOSFOMYCIN (includes G-6-p) FOS 200 µg 250 Discs
9109/1	FOSFOMYCIN (includes G-6-p) FOS 200 µg 50 Discs
9110	TRIMETHOPRIM TM 5 µg 250 Discs
9110/1	TRIMETHOPRIM TM 5 µg 50 Discs
9111	FUSIDIC ACID FC 30 µg 250 Discs
9111/1	FUSIDIC ACID FC 30 µg 50 Discs
9112	CEFPROZIL CPR 30 µg 250 Discs
9112/1	CEFPROZIL CPR 30 µg 50 Discs
9113	LOMEFLOXACIN LOM 10 µg 250 Discs
9113/1	LOMEFLOXACIN LOM 10 µg 50 Discs
9115	AMPICILLIN AMP 2 µg 250 Discs
9115/1	AMPICILLIN AMP 2 µg 50 Discs
9116	LINCOMYCIN MY 15 µg 250 Discs
9116/1	LINCOMYCIN MY 15 µg 50 Discs
9117	NOVOBIOCIN NO 5 µg 250 Discs
9117/1	NOVOBIOCIN NO 5 µg 50 Discs
9118	RIFAMPICIN RD 5 µg 250 Discs
9118/1	RIFAMPICIN RD 5µg 50 Discs
9119	METRONIDAZOLE MTZ 50 µg 250 Discs
9119/1	METRONIDAZOLE MTZ 50 µg 50 Discs
9120	POLYMYXIN B PB 300 UI 250 Discs
9120/1	POLYMYXIN B PB 300 UI 50 Discs
9121	FOSFOMYCIN (includes G-6-p) FOS 100 µg 250 Discs
9121/1	FOSFOMYCIN (includes G-6-p) FOS 100 µg 50 Discs
9122	AMPLICLOX (Ampicillin-Cloxacillin) ACL 30 µg 250 Discs
9122/1	AMPLICLOX (Ampicillin-Cloxacillin) ACL 30 µg 50 Discs
9124	GENTAMICIN CN 120 µg 250 Discs
9124/1	GENTAMICIN CN 120 µg 50 Discs
9125	GENTAMICIN CN 30 µg 250 Discs
9125/1	GENTAMICIN CN 30 µg 50 Discs
9126	SULFONAMIDE S3 300 µg 250 Discs
9126/1	SULFONAMIDE S3 300 µg 50 Discs
9127	PENICILLIN G P 2 IU 250 Discs
9127/1	PENICILLIN G P 2 IU 50 Discs
9128	CHLORAMPHENICOL C 10 µg 250 Discs
9128/1	CHLORAMPHENICOL C 10 µg 50 Discs
9129	SULBACTAM SU 20µg 250 Discs
9129/1	SULBACTAM SU 20µg 50 Discs
9130	PENICILLIN G P 1 IU 250 Discs
9130/1	PENICILLIN G P 1 IU 50 Discs
9131	SODIUM FUSIDATE FC 30 250 Discs
9132	SULFAPRIM SXT 50 µg 250 Discs
9132/1	SULFAPRIM SXT 50 µg 50 Discs
9133	AMOXICILLIN AML 10 µg 250 Discs
9133/1	AMOXICILLIN AML 10 µg 50 Discs
9134	CEFOTAXIME CTX 75 µg 250 Discs
9134/1	CEFOTAXIME CTX 75 µg 50 Discs
9135	OXACILLIN OX 5µg 250 Discs
9135/1	OXACILLIN OX 5µg 50 Discs
9136	LINEZOLID LNZ 30µg 250 Discs
9136/1	LINEZOLID LNZ 30µg 50 Discs
9137	AMPHOTERICIN B AMB 10 µg 250 Discs
9137/1	AMPHOTERICIN B AMB 10 µg 50 Discs
9139	ITRACONAZOLE ITC 8 µg 250 Discs
9139/1	ITRACONAZOLE ITC 8 µg 50 Discs
9140	KETOCONAZOLE KCA 15 µg 250 Discs
9140/1	KETOCONAZOLE KCA 15 µg 50 Discs
9141	COLISTIN SULFATE CS 30 UI 250 Discs
9141/1	COLISTIN SULFATE CS 30 UI 50 Discs
9142	STREPTOMYCIN S 300 µg 250 Discs
9142/1	STREPTOMYCIN S 300 µg 50 Discs
9143	CEFEPIME+CLAVULANIC ACID FEL 40 µg 250 Discs
9144	Cefoxitin+Cloxacillin FOC 230 µg 250 Discs
9144/1	Cefoxitin+Cloxacillin FOC 230 µg 50 Discs
9145	CEFTAZIDIME+CLAVULANIC ACID CAL 40 µg 250 Discs
9145/1	CEFTAZIDIME+CLAVULANIC ACID CAL 40 µg 50 Discs
9146	CLINDAMYCIN CD 10 µg 250 Discs
9146/1	CLINDAMYCIN CD 10 µg 50 Discs
9147	TIGECYCLIN TGC 15 µg 250 Discs
9147/1	TIGECYCLIN TGC 15 µg 50 Discs
9148	FLUCYTOSINE AFY 10 µg 250 Discs
9148/1	FLUCYTOSINE AFY 10 µg 50 Discs
9150	SULFADIAZINE SUZ 300 ug 250 Discs
9150/1	SULFADIAZINE SUZ 300 ug 50 Discs
9151	AMOXICILLIN AML 2 µg 250 Discs
9151/1	AMOXICILLIN AML 2 µg 50 Discs
9152	CEFOTAXIME CTX 5 µg 250 Discs
9152/1	CEFOTAXIME CTX 5 µg 50 Discs
9153	CEFTAZIDIME CAZ 10 µg 250 Discs
9153/1	CEFTAZIDIME CAZ 10 µg 50 Discs
9154	DORIPENEM DOR 10 µg 250 Discs
9154/1	DORIPENEM DOR 10 µg 50 Discs
9155	LINEZOLID LNZ 10 µg 250 Discs
9155/1	LINEZOLID LNZ 10 µg 50 Discs
9156	MECILLINAM MEC 10 µg 250 Discs
9156/1	MECILLINAM MEC 10 µg 50 Discs
9157	MUPIROCIN MUP 200 µg 250 Discs
9157/1	MUPIROCIN MUP 200 µg 50 Discs
9158	NITROFURANTOIN F 100 µg 250 Discs
9158/1	NITROFURANTOIN F 100 µg 50 Discs
9159	PIPERACILLIN PRL 30 µg 250 Discs
9159/1	PIPERACILLIN PRL 30 µg 50 Discs
9160	PIPERACILLIN-TAZOBACTAM TZP 36 µg 250 Discs
9160/1	PIPERACILLIN-TAZOBACTAM TZP 36 µg 50 Discs
9161	QUINUPRISTIN-DALFOPRISTIN QDA 15 µg 250 Discs
9161/1	QUINUPRISTIN-DALFOPRISTIN QDA 15 µg 50 Discs
9162	STREPTOMYCIN S 300 µg 250 Discs
9162/1	STREPTOMYCIN S 300 µg 50 Discs
9163	TOBRAMYCIN TOB 30 ug 250 Discs
9163/1	TOBRAMYCIN TOB 30 ug 50 Discs
9164	VANCOMYCIN VA 5 µg 250 Discs
9164/1	VANCOMYCIN VA 5 µg 50 Discs
9165	CASPOFUNGIN CAS 5 µg 250 Discs
9165/1	CASPOFUNGIN CAS 5 µg 50 Discs
9166	FLUCONAZOLE FLU 25 µg 250 Discs
9166/1	FLUCONAZOLE FLU 25 µg 50 Discs
9167	POSACONAZOLE POS 5 µg 250 Discs
9167/1	POSACONAZOLE POS 5 µg 50 Discs
9168	VORICONAZOLE VO 1 µg 250 Discs
9168/1	VORICONAZOLE VO 1 µg 50 Discs
9169	GATIFLOXACIN GAT 5 µg 250 Discs
9169/1	GATIFLOXACIN GAT 5 µg 50 Discs
9170	NETILMICIN NET 10 µg 250 Discs
9170/1	NETILMICIN NET 10 µg 50 Discs
9171	PHENOXYMETHYLPENICILLIN PV 10 µg 250 Discs
9171/1	PHENOXYMETHYLPENICILLIN PV 10 µg 50 Discs
9172	TELITHROMYCIN TEL 15 µg 250 Discs
9172/1	TELITHROMYCIN TEL 15 µg 50 Discs
9173	LORACARBEF LOR 30 µg 250 Discs
9173/1	LORACARBEF LOR 30 µg 50 Discs

9174	NAFCILLIN NAF 1 µg 250 Discs
9174/1	NAFCILLIN NAF 1 µg 50 Discs
9175	MEROPENEM+CLOXACILLIN MR+CL 250 Discs
9175/1	MEROPENEM+CLOXACILLIN MR+CL 50 Discs
9176	Meropenem + Phenylboronic acid MR + BO 250 Discs
9176/1	Meropenem + Phenylboronic acid MR + BO 50 Discs
9177	MEROPENEM+DIPICOLINIC ACID MR+DP 250 Discs
9177/1	MEROPENEM+DIPICOLINIC ACID MR+DP 50 Discs
9178	Meropenem + EDTA MR + ED 250 Discs
9178/1	Meropenem + EDTA MR + ED 50 Discs
9179	AMOXICILLIN AML 25 µg 250 Discs
9179/1	AMOXICILLIN AML 25 µg 50 Discs
9181	NITROFURANTOIN F 50 µg 250 Discs
9181/1	NITROFURANTOIN F 50 µg 50 Discs
9182	CEFOTAXIME+CLAVULANIC ACID CTL 40 µg 250 Discs
9182/1	CEFOTAXIME+CLAVULANIC ACID CTL 40 µg 50 Discs
9183	Imipenem + EDTA IMI + ED 250 Discs
9183/1	Imipenem + EDTA IMI + ED 50 Discs
9184	COLISTIN SULFATE CS 25 µg 250 Discs
9184/1	COLISTIN SULFATE CS 25 µg 50 Discs
9185	CEFPIROME CR 30 µg 250 Discs
9185/1	CEFPIROME CR 30 µg 50 Discs
9186	TEMOCILLIN TMO 30 µg 250 Discs
9186/1	TEMOCILLIN TMO 30 µg 50 Discs
9187	Sulfamethoxazole SMX 100 µg 250 Discs
9187/1	Sulfamethoxazole SMX 100 µg 50 Discs
9188	Metronidazole MTZ 10 µg 250 Discs
9188/1	Metronidazole MTZ 10 µg 50 Discs
9189	MUPIROCIN MUP 5 µg 250 Discs
9190	CEFPODOXIME+CLAVULANIC ACID PXL 11 µg 250 Discs
9190/1	CEFPODOXIME+CLAVULANIC ACID PXL 11 µg 50 Discs
9191	AMOXICILLIN-CLAVULANIC ACID AUG 3 µg 250 Discs
9191/1	AMOXICILLIN-CLAVULANIC ACID AUG 3 µg 50 Discs
9192	ROKITAMYCIN ROK 30 µg 250 Discs
9192/1	ROKITAMYCIN ROK 30 µg 50 Discs
9193	Phenylboronic acid BO 250 Discs
9193/1	Phenylboronic acid BO 50 Discs
9194	DIPICOLINIC ACID DP 250 Discs
9194/1	DIPICOLINIC ACID DP 50 Discs
9195	CEFTAROLINE CPT 5 µg 250 Discs
9195/1	CEFTAROLINE CPT 5 µg 50 Discs
9198	CEFTAROLINE CPT 30 µg 250 Discs
9198/1	CEFTAROLINE CPT 30 µg 50 Discs
9199	ERTAPENEM+CLOXACILLIN ET+CL 250 Discs
9199/1	ERTAPENEM+CLOXACILLIN ET+CL 50 Discs
9201	ORITAVANCIN ORI 25 µg 250 Discs
9201/1	ORITAVANCIN ORI 25 µg 50 Discs
9202	Ertapenem+Phenylboronic acid ET+BO 250 Discs
9202/1	Ertapenem+Phenylboronic acid ET+BO 50 Discs
9203	Cefotaxime+Clavulanic acid+Cloxacillin CTLC 250 Discs
9203/1	Cefotaxime+Clavulanic acid+Cloxacillin CTLC 50 Discs
9204	Ceftazidime+Clavulanic acid+Cloxacillin CALC 250 Discs
9204/1	Ceftazidime+Clavulanic acid+Cloxacillin CALC 50 Discs
9205	Ceftazime-avibactam CZA 50 µg 250 Discs
9205/1	Ceftazime-avibactam CZA 50 µg 50 Discs
9206	Ceftazime-avibactam CZA 14 µg 250 Discs
9206/1	Ceftazime-avibactam CZA 14 µg 50 Discs
9207	Ulifloxacin ULI 5 µg 250 Discs
9207/1	Ulifloxacin ULI 5 µg 50 Discs

91200	DISC DISPENSER 8 CARTRIDGES
91203	DISC DISPENSER 6 CARTRIDGES
92000	AMOX*/SULB 2/1 AXS 0.016-256* 30 MIC Tests
920000	AMOX*/SULB 2/1 AXS 0.016-256* 100 MIC Tests
92001	RIFAMPICIN RD 0.002-32 30 MIC Tests
920010	RIFAMPICIN RD 0.002-32 100 MIC Tests
920011	RIFAMPICIN RD 0.002-32 10 MIC Tests
92002	FUSIDIC ACID FU 0.016-256 30 MIC Tests
920020	FUSIDIC ACID FU 0.016-256 100 MIC Tests
920021	FUSIDIC ACID FU 0.016-256 10 MIC Tests
92003	AMPICILLIN AMP 0.016-256 30 MIC Tests
920030	AMPICILLIN AMP 0.016-256 100 MIC Tests
920031	AMPICILLIN AMP 0.016-256 10 MIC Tests
92004	POLYMYXIN B PB 0.064-1024 30 MIC Tests
920040	POLYMYXIN B PB 0.064-1024 100 MIC Tests
920041	POLYMYXIN B PB 0.064-1024 10 MIC Tests
92005	CEFPODOXIME PX 0.016-256 30 MIC Tests
920050	CEFPODOXIME PX 0.016-256 100 MIC Tests
920051	CEFPODOXIME PX 0.016-256 10 MIC Tests
92006	CEFOTAXIME CTX 0.016-256 30 MIC Tests
920060	CEFOTAXIME CTX 0.016-256 100 MIC Tests
920061	CEFOTAXIME CTX 0.016-256 10 MIC Tests
92007	CEFOTAXIME CTX 0.002-32 30 MIC Tests
920070	CEFOTAXIME CTX 0.002-32 100 MIC Tests
920071	CEFOTAXIME CTX 0.002-32 10 MIC Tests
92008	CEFPIROME CR 0.016-256 30 MIC Tests
920080	CEFPIROME CR 0.016-256 100 MIC Tests
920081	CEFPIROME CR 0.016-256 10 MIC Tests
92009	GENTAMICIN CN 0.016-256 30 MIC Tests
920090	GENTAMICIN CN 0.016-256 100 MIC Tests
920091	GENTAMICIN CN 0.016-256 10 MIC Tests
92010	GENTAMICIN CN 0.064-1024 30 MIC Tests
920100	GENTAMICIN CN 0.064-1024 100 MIC Tests
920101	GENTAMICIN CN 0.064-1024 10 MIC Tests
92011	GATIFLOXACIN GAT 0.002-32 30 MIC Tests
920110	GATIFLOXACIN GAT 0.002-32 100 MIC Tests
920111	GATIFLOXACIN GAT 0.002-32 10 MIC Tests
92012	TEICOPLANIN TEC 0.016-256 30 MIC Tests
920120	TEICOPLANIN TEC 0.016-256 100 MIC Tests
920121	TEICOPLANIN TEC 0.016-256 10 MIC Tests
92013	ENROFLOXACIN ENR 0.002-32 30 MIC Tests
920130	ENROFLOXACIN ENR 0.002-32 100 MIC Tests
920131	ENROFLOXACIN ENR 0.002-32 10 MIC Tests
92014	SPECTINOMYCIN SPC 0.064-1024 30 MIC Tests
920140	SPECTINOMYCIN SPC 0.064-1024 100 MIC Tests
920141	SPECTINOMYCIN SPC 0.064-1024 10 MIC Tests
92015	OXACILLIN OX 0.016-256 30 MIC Tests
920150	OXACILLIN OX 0.016-256 100 MIC Tests
920151	OXACILLIN OX 0.016-256 10 MIC Tests
92016	CEFTIZOXIME CZX 0.016-256 30 MIC Tests
920160	CEFTIZOXIME CZX 0.016-256 100 MIC Tests
920161	CEFTIZOXIME CZX 0.016-256 10 MIC Tests
92017	MECILLINAM MEC 0.002-32 30 MIC Tests
920170	MECILLINAM MEC 0.002-32 100 MIC Tests
920171	MECILLINAM MEC 0.002-32 10 MIC Tests
92018	AMIKACIN AK 0.016-256 30 MIC Tests
920180	AMIKACIN AK 0.016-256 100 MIC Tests
920181	AMIKACIN AK 0.016-256 10 MIC Tests
92019	BACITRACIN BA 0.016-256 30 MIC Tests
920190	BACITRACIN BA 0.016-256 100 MIC Tests

920191	BACITRACIN BA 0.016-256 10 MIC Tests
92020	CEFOTETAN CTT 0.016-256 30 MIC Tests
920200	CEFOTETAN CTT 0.016-256 100 MIC Tests
920201	CEFOTETAN CTT 0.016-256 10 MIC Tests
92021	AMOXICILLIN AML 0.016-256 30 Tests
920210	AMOXICILLIN AML 0.016-256 100 MIC Tests
920211	AMOXICILLIN AML 0.016-256 10 MIC Tests
92022	NITROFURANTOIN F 0.032-512 30 MIC Tests
920220	NITROFURANTOIN F 0.032-512 100 MIC Tests
920221	NITROFURANTOIN F 0.032-512 10 MIC Tests
92023	CEFOB*/SULB 2/1 CPS 0.016-256* 30 MIC Tests
920230	CEFOB*/SULB 2/1 CPS 0.016-256* 100 MIC Tests
920231	CEFOB*/SULB 2/1 CPS 0.016-256* 10 MIC Tests
92024	AMOX*/CLAV 2/1 AMG 0.016-256* 30 MIC Tests
920240	AMOX*/CLAV 2/1 AMG 0.016-256* 100 MIC Tests
920241	AMOX*/CLAV 2/1 AMG 0.016-256* 10 MIC Tests
92025	RIFAMPICIN RD 0.016-256 30 MIC Tests
920250	RIFAMPICIN RD 0.016-256 100 MIC Tests
920251	RIFAMPICIN RD 0.016-256 10 MIC Tests
92026	QUIN-DALFOPRIST QDA 0.002-32 30 MIC Tests
920260	QUIN-DALFOPRIST QDA 0.002-32 100 MIC Tests
920261	QUIN-DALFOPRIST QDA 0.002-32 10 MIC Tests
92027	AMPIC*/SULB 2/1 AMS 0.016-256* 30 MIC Tests
920270	AMPIC*/SULB 2/1 AMS 0.016-256* 100 MIC Tests
920271	AMPIC*/SULB 2/1 AMS 0.016-256* 10 MIC Tests
92028	SULBACTAM SUL 0.016-256 30 MIC Tests
920280	SULBACTAM SUL 0.016-256 100 MIC Tests
920281	SULBACTAM SUL 0.016-256 10 MIC Tests
92029	TEMOCILLIN TMO 0.064-1024 30 MIC Tests
920290	TEMOCILLIN TMO 0.064-1024 100 MIC Tests
920291	TEMOCILLIN TMO 0.064-1024 10 MIC Tests
92030	AZITHROMYCIN AZM 0.016-256 30 MIC Tests
920300	AZITHROMYCIN AZM 0.016-256 100 MIC Tests
920301	AZITHROMYCIN AZM 0.016-256 10 MIC Tests
92031	SULFAMETOXAZOLE SMX 0.064-1024 30 MIC Tests
920310	SULFAMETOXAZOLE SMX 0.064-1024 100 MIC Tests
920311	SULFAMETOXAZOLE SMX 0.064-1024 10 MIC Tests
92032	MINOCYCLINE MN 0.016-256 30 MIC Tests
920320	MINOCYCLINE MN 0.016-256 100 MIC Tests
920321	MINOCYCLINE MN 0.016-256 10 MIC Tests
92033	AZTREONAM ATM 0.016-256 30 MIC Tests
920330	AZTREONAM ATM 0.016-256 100 MIC Tests
920331	AZTREONAM ATM 0.016-256 10 MIC Tests
92034	KANAMYCIN K 0.016-256 30 MIC Tests
920340	KANAMYCIN K 0.016-256 100 MIC Tests
920341	KANAMYCIN K 0.016-256 10 MIC Tests
92035	GEMIFLOXACIN GEM 0.002-32 30 MIC Tests
920350	GEMIFLOXACIN GEM 0.002-32 100 MIC Tests
920351	GEMIFLOXACIN GEM 0.002-32 10 MIC Tests
92036	CEFACLOR CEC 0,016-256 30 MIC Tests
920360	CEFACLOR CEC 0,016-256 100 MIC Tests
920361	CEFACLOR CEC 0,016-256 10 MIC Tests
92037	TRIMETHOPRIM TM 0.002-32 30 MIC Tests
920370	TRIMETHOPRIM TM 0.002-32 100 MIC Tests
920371	TRIMETHOPRIM TM 0.002-32 10 MIC Tests
92038	MUPIROCIN MUP 0.064-1024 30 MIC Tests
920380	MUPIROCIN MUP 0.064-1024 100 MIC Tests
920381	MUPIROCIN MUP 0.064-1024 10 MIC Tests
92039	CEPHALOTHIN KF 0.016-256 30 MIC Tests
920390	CEPHALOTHIN KF 0.016-256 100 MIC Tests
920391	CEPHALOTHIN KF 0.016-256 10 MIC Tests
92040	DORIPENEM DOR 0.002-32 30 MIC Tests
920400	DORIPENEM DOR 0.002-32 100 MIC Tests
920401	DORIPENEM DOR 0.002-32 10 MIC Tests
92041	Pefloxacin PEF 0.016-256 mg/L 30 MIC Tests
920410	Pefloxacin PEF 0.016-256 mg/L 100 MIC Tests
920411	Pefloxacin PEF 0.016-256 mg/L 10 MIC Tests
92042	CEFTRIAXONE CRO 0.016-256 30 MIC Tests
920420	CEFTRIAXONE CRO 0.016-256 100 MIC Tests
920421	CEFTRIAXONE CRO 0.016-256 10 MIC Tests
92043	CEFTRIAXONE CRO 0.002-32 30 MIC Tests
920430	CEFTRIAXONE CRO 0.002-32 100 MIC Tests
920431	CEFTRIAXONE CRO 0.002-32 10 MIC Tests
92044	CLOXACILLIN CX 0.016-256 30 MIC Tests
920440	CLOXACILLIN CX 0.016-256 100 MIC Tests
920441	CLOXACILLIN CX 0.016-256 10 MIC Tests
92045	CIPROFLOXACIN CIP 0.002-32 30 MIC Tests
920450	CIPROFLOXACIN CIP 0.002-32 100 MIC Tests
920451	CIPROFLOXACIN CIP 0.002-32 10 MIC Tests
92046	SPIRAMYCIN SP 0.002-32 30 MIC Tests
920460	SPIRAMYCIN SP 0.002-32 100 MIC Tests
920461	SPIRAMYCIN SP 0.002-32 10 MIC Tests
92048	CLARITHROMYCIN CLR 0.016-256 30 MIC Tests
920480	CLARITHROMYCIN CLR 0.016-256 100 MIC Tests
920481	CLARITHROMYCIN CLR 0.016-256 10 MIC Tests
92049	CEFTAROLINE CPT 0.016-256 30 MIC Test
920490	CEFTAROLINE CPT 0.016-256 100 MIC Test
920491	CEFTAROLINE CPT 0.016-256 10 MIC Test
92050	FOSMIDOMYCIN FOM 0.016-256 30 MIC Tests
920500	FOSMIDOMYCIN FOM 0.016-256 100 MIC Tests
920501	FOSMIDOMYCIN FOM 0.016-256 10 MIC Tests
92051	ERYTHROMYCIN E 0.016-256 30 MIC Tests
920510	ERYTHROMYCIN E 0.016-256 100 MIC Tests
920511	ERYTHROMYCIN E 0.016-256 10 MIC Tests
92052	TELAVANCIN TLV 0.002-32 30 MIC Tests
920520	TELAVANCIN TLV 0.002-32 100 MIC Tests
920521	TELAVANCIN TLV 0.002-32 10 MIC Tests
92053	TELAVANCIN TLV 0.016-256 30 MIC Tests
920530	TELAVANCIN TLV 0.016-256 100 MIC Tests
920531	TELAVANCIN TLV 0.016-256 10 MIC Tests
92054	IMIPENEM IMI 0.002-32 30 MIC Tests
920540	IMIPENEM IMI 0.002-32 100 MIC Tests
920541	IMIPENEM IMI 0.002-32 10 MIC Tests
92056	Ceftaroline CPT 0.002-32 30 MIC Tests
920560	Ceftaroline CPT 0.002-32 100 MIC Tests
920561	Ceftaroline CPT 0.002-32 10 MIC Tests
92057	VANCOMYCIN VA 0.016-256 30 MIC Tests
920570	VANCOMYCIN VA 0.016-256 100 MIC Tests
920571	VANCOMYCIN VA 0.016-256 10 MIC Tests
92058	CEFTIBUTEN CTB 0.002-32 30 MIC Tests
920580	CEFTIBUTEN CTB 0.002-32 100 MIC Tests
920581	CEFTIBUTEN CTB 0.002-32 10 MIC Tests
92060	CEFIXIME CFM 0,016-256 30 MIC Tests
920600	CEFIXIME CFM 0,016-256 100 MIC Tests
920601	CEFIXIME CFM 0,016-256 10 MIC Tests
92066	CEFOXITIN FOX 0.016-256 30 MIC Tests
920660	CEFOXITIN FOX 0.016-256 100 MIC Tests
920661	CEFOXITIN FOX 0.016-256 10 MIC Tests
92072	CLINDAMYCIN CD 0.016-256 30 MIC Tests
920720	CLINDAMYCIN CD 0.016-256 100 MIC Tests

920721	CLINDAMYCIN CD 0.016-256 10 MIC Tests
92075	CHLORAMPHENICOL C 0,016-256 30 MIC Tests
920750	CHLORAMPHENICOL C 0,016-256 100 MIC Tests
920751	CHLORAMPHENICOL C 0,016-256 10 MIC Tests
92078	FOSFOMYCIN FOS 0,016-256 30 MIC Tests
920780	FOSFOMYCIN FOS 0,016-256 100 MIC Tests
920781	FOSFOMYCIN FOS 0,016-256 10 MIC Tests
92079	FOSFOMYCIN FOS 0,064-1024 30 MIC Tests
920790	FOSFOMYCIN FOS 0,064-1024 100 MIC Tests
920791	FOSFOMYCIN FOS 0,064-1024 10 MIC Tests
92081	LEVOFLOXACIN LEV 0.002-32 30 MIC Tests
920810	LEVOFLOXACIN LEV 0.002-32 100 MIC Tests
920811	LEVOFLOXACIN LEV 0.002-32 10 MIC Tests
92084	MEROPENEM MRP 0.002-32 30 MIC Tests
920840	MEROPENEM MRP 0.002-32 100 MIC Tests
920841	MEROPENEM MRP 0.002-32 10 MIC Tests
92087	METRONIDAZOLE MTZ 0.016-256 30 MIC Tests
920870	METRONIDAZOLE MTZ 0.016-256 100 MIC Tests
920871	METRONIDAZOLE MTZ 0.016-256 10 MIC Tests
92090	MOXIFLOXACIN MXF 0,002-32 30 MIC Tests
920900	MOXIFLOXACIN MXF 0,002-32 100 MIC Tests
920901	MOXIFLOXACIN MXF 0,002-32 10 MIC Tests
92093	NETILMICIN NET 0.016-256 30 MIC Tests
920930	NETILMICIN NET 0.016-256 100 MIC Tests
920931	NETILMICIN NET 0.016-256 10 MIC Tests
92096	NORFLOXACIN NOR 0.016-256 30 MIC Tests
920960	NORFLOXACIN NOR 0.016-256 100 MIC Tests
920961	NORFLOXACIN NOR 0.016-256 10 MIC Tests
92099	OFLOXACIN OFX 0.002-32 30 MIC Tests
920990	OFLOXACIN OFX 0.002-32 100 MIC Tests
920991	OFLOXACIN OFX 0.002-32 10 MIC Tests
92102	PENICILLIN G P 0.016-256 30 MIC Tests
921020	PENICILLIN G P 0.016-256 100 MIC Tests
921021	PENICILLIN G P 0.016-256 10 MIC Tests
92103	PENICILLIN G P 0.002-32 30 MIC Tests
921030	PENICILLIN G P 0.002-32 100 MIC Tests
921031	PENICILLIN G P 0.002-32 10 MIC Tests
92105	PIPERACILLIN PIP 0.016-256 30 MIC Tests
921050	PIPERACILLIN PIP 0.016-256 100 MIC Tests
921051	PIPERACILLIN PIP 0.016-256 10 MIC Tests
92108	PIPERAC*/TAZOB TZP 0.016-256* 30 MIC Tests
921080	PIPERAC*/TAZOB TZP 0.016-256* 100 MIC Tests
921081	PIPERAC*/TAZOB TZP 0.016-256* 10 MIC Tests
92111	STREPTOMYCIN S 0.064-1024 30 Tests
921110	STREPTOMYCIN S 0.064-1024 100 MIC Tests
921111	STREPTOMYCIN S 0.064-1024 10 MIC Tests
92112	Streptomycin S 0.016-256 mg/L 30 Tests
921120	Streptomycin S 0.016-256 mg/L 100 MIC Tests
921121	Streptomycin S 0.016-256 mg/L 10 MIC Tests
92114	TETRACYCLINE TE 0.016-25 30 MIC Tests
921140	TETRACYCLINE TE 0.016-25 100 MIC Tests
921141	TETRACYCLINE TE 0.016-25 10 MIC Tests
92117	TICARC*/CLAV TTC 0,016-256* 30MICTests
921170	TICARC*/CLAV TTC 0,016-256* 100 MIC Test
921171	TICARC*/CLAV TTC 0,016-256* 10 MIC Test
92120	TOBRAMYCIN TOB 0,064-1024 30 MIC Tests
921200	TOBRAMYCIN TOB 0,064-1024 100 MIC Tests
921201	TOBRAMYCIN TOB 0,064-1024 10 MIC Tests
92121	TOBRAMYCIN TOB 0,016-256 30 Tests
921210	TOBRAMYCIN TOB 0,016-256 100 Tests
921211	TOBRAMYCIN TOB 0,016-256 10 Tests
92123	TRIM*/SULFAM SXT 0,002-32 30 MIC Tests
921230	TRIM*/SULFAM SXT 0,002-32 100 MIC Tests
921231	TRIM*/SULFAM SXT 0,002-32 10 MIC Tests
92126	CEFEPIME FEP 0.016-256 30 MIC Tests
921260	CEFEPIME FEP 0.016-256 100 MIC Tests
921261	CEFEPIME FEP 0.016-256 10 MIC Tests
92127	CEFEPIME FEP 0.002-32 µg/ml 30 MIC Tests
921270	CEFEPIME FEP 0.002-32 µg/ml 100 MIC Tests
921271	CEFEPIME FEP 0.002-32 µg/ml 10 MIC Tests
92129	CEFUROXIME CXM 0.016-256 30 MIC Tests
921290	CEFUROXIME CXM 0.016-256 100 MIC Tests
921291	CEFUROXIME CXM 0.016-256 10 MIC Tests
92132	NALIDIXIC ACID NA 0,016-256 30 MIC Tests
921320	NALIDIXIC ACID NA 0,016-256 100 MIC Tests
921321	NALIDIXIC ACID NA 0,016-256 10 MIC Tests
92135	LINEZOLID LNZ 0.016-256 30 MIC Tests
921350	LINEZOLID LNZ 0.016-256 100 MIC Tests
921351	LINEZOLID LNZ 0.016-256 10 MIC Tests
92136	TEDIZOLID TZD 0.002-32 30 MIC Tests
921360	TEDIZOLID TZD 0.002-32 100 MIC Tests
921361	TEDIZOLID TZD 0.002-32 10 MIC Tests
92137	Dalbavancin DAL 0.002-32 30 MIC Tests
921370	Dalbavancin DAL 0.002-32 100 MIC Tests
921371	Dalbavancin DAL 0.002-32 10 MIC Tests
92138	CEFTAZIDIME CAZ 0.016-256 30 MIC Tests
921380	CEFTAZIDIME CAZ 0.016-256 100 MIC Tests
921381	CEFTAZIDIME CAZ 0.016-256 10 MIC Tests
92140	Ceftobiprole BPR 0.002-32 mg/L 30 MIC Tests
921400	Ceftobiprole BPR 0.002-32 mg/L 100 MIC Tests
921401	Ceftobiprole BPR 0.002-32 mg/L 10 MIC Tests
92141	COLISTIN CS 0.016-256 30 MIC Tests
921410	COLISTIN CS 0.016-256 100 MIC Tests
921411	COLISTIN CS 0.016-256 10 MIC Tests
92142	COLISTIN CS 0.064-1024 30 MIC Tests
921420	COLISTIN CS 0.064-1024 100 MIC Tests
921421	COLISTIN CS 0.064-1024 10 MIC Tests
92144	TIGECYCLIN TGC 0.016-256 30 MIC Tests
921440	TIGECYCLIN TGC 0.016-256 100 MIC Tests
921441	TIGECYCLIN TGC 0.016-256 10 MIC Tests
92145	DAPTOMYCIN DAP 0.016-256 30 MIC Tests
921450	DAPTOMYCIN DAP 0.016-256 100 MIC Tests
921451	DAPTOMYCIN DAP 0.016-256 10 MIC Tests
92146	Ceftolozane*-tazobactam C/T 0.016-256* mg/L 30 MIC Tests
921460	Ceftolozane*-tazobactam C/T 0.016-256* mg/L 100 MIC Tests
921461	Ceftolozane*-tazobactam C/T 0.016-256* mg/L 10 MIC Tests
92147	FLUCONAZOLE FLU 0.016-256 30 MIC Tests
921470	FLUCONAZOLE FLU 0.016-256 100 MIC Tests
921471	FLUCONAZOLE FLU 0.016-256 10 MIC Tests
92148	ITRACONAZOLE ITC 0.002-32 30 MIC Tests
921480	ITRACONAZOLE ITC 0.002-32 100 MIC Tests
921481	ITRACONAZOLE ITC 0.002-32 10 MIC Tests
92149	FLUCYTOSIN FC 0.002-32 30 MIC Tests
921490	FLUCYTOSIN FC 0.002-32 100 MIC Tests
921491	FLUCYTOSIN FC 0.002-32 10 MIC Tests
92150	VORICONAZOLE VO 0.002-32 30 MIC Tests
921500	VORICONAZOLE VO 0.002-32 100 MIC Tests
921501	VORICONAZOLE VO 0.002-32 10 MIC Tests
92151	KETOCONAZOLE KE 0.002-32 30 MIC Tests

921510	KETOCONAZOLE KE 0.002-32 100 MIC Tests
921511	KETOCONAZOLE KE 0.002-32 10 MIC Tests
92152	POSACONAZOLE POS 0,002-32 30 MIC Tests
921520	POSACONAZOLE POS 0,002-32 100 MIC Tests
921521	POSACONAZOLE POS 0,002-32 10 MIC Tests
92153	AMPHOTERICIN B AMB 0,002-32 30 MIC Tests
921530	AMPHOTERICIN B AMB 0,002-32 100 MIC Tests
921531	AMPHOTERICIN B AMB 0,002-32 10 MIC Tests
92154	CASPOFUNGIN CAS 0,002-32 30 MIC Tests
921540	CASPOFUNGIN CAS 0,002-32 100 MIC Tests
921541	CASPOFUNGIN CAS 0,002-32 10 MIC Tests
92155	ANIDULAFUNGIN AND 0.002-32 30 MIC Tests
921550	ANIDULAFUNGIN AND 0.002-32 100 MIC Tests
921551	ANIDULAFUNGIN AND 0.002-32 10 MIC Tests
92156	DOXYCYCLINE DXT 0,016-256 30 MIC Tests
921560	DOXYCYCLINE DXT 0,016-256 100 MIC Tests
921561	DOXYCYCLINE DXT 0,016-256 10 MIC Tests
92157	ERTAPENEM ETP 0,002-32 30 MIC Tests
921570	ERTAPENEM ETP 0,002-32 100 MIC Tests
921571	ERTAPENEM ETP 0,002-32 10 MIC Tests
92159	CEFTAZ/CEFTAZ+CLAV. CAZ/CAL MIC 30 Tests
921590	CEFTAZ/CEFTAZ+CLAV. CAZ/CAL MIC 100 Tests
921591	CEFTAZ/CEFTAZ+CLAV. CAZ/CAL MIC 10 Tests
92160	CEFOT./CEFOT.+ CLAV. CTX/CTL 30 MIC Tests
921600	CEFOT./CEFOT.+ CLAV. CTX/CTL 100 MIC Tests
921601	CEFOT./CEFOT.+ CLAV. CTX/CTL 10 MIC Tests
92161	CEFEP./CEFEP.+CLAV. FEP/FEL 30 MIC Tests
921610	CEFEP./CEFEP.+CLAV. FEP/FEL 100 MIC Tests
921611	CEFEP./CEFEP.+CLAV. FEP/FEL 10 MIC Tests
92162	IMIPEN./IMIP.+ EDTA IMI/IMD 30 MIC Tests
921620	IMIPEN./IMIP.+ EDTA IMI/IMD 100 MIC Tests
921621	IMIPEN./IMIP.+ EDTA IMI/IMD 10 MIC Tests
92163	VANCOM/TEICOPLANINA VA/TEC 30 MIC Tests
921630	VANCOM/TEICOPLANINA VA/TEC 100 MIC Tests
921631	VANCOM/TEICOPLANINA VA/TEC 10 MIC Tests
92164	CEFOT/CEFOT+CLOX CTT/CXT0,5-32/0,5-32 30 MIC Tests
921640	CEFOT/CEFOT+CLOX CTT/CXT 0,5-32/0,5-32 100 MIC Tests
921641	CEFOT/CEFOT+CLOX CTT/CXT 0,5-32/0,5-32 10 MIC Tests
92165	MEROPENEM/MEROPENEM + EDTA MRP/MRD 0.125-8/0.032-2 µg/ml 30 MIC Tests
921650	MEROPENEM/MEROPENEM + EDTA MRP/MRD 0.125-8/0.032-2 µg/ml 100 MIC Tests
921651	MEROPENEM/MEROPENEM + EDTA MRP/MRD 0.125-8/0.032-2 µg/ml 10 MIC Tests
92166	IMIPEN/IMIP+EDTA IMI/IMD 0.125-8/0.032-2 30 MIC Tests
921660	IMIPEN/IMIP+EDTA IMI/IMD 0.125-8/0.032-2 100 MIC Tests
921661	IMIPEN/IMIP+EDTA IMI/IMD 0.125-8/0.032-2 10 MIC Tests
92167	MEROPENEM / MEROPENEM + PHENYLBORONIC ACID MRP/MBO 0.125-8 / 0.032-2 30 MIC Tests
921670	MEROPENEM / MEROPENEM + PHENYLBORONIC ACID MRP/MBO 0.125-8 / 0.032-2 100 MIC Tests
921671	MEROPENEM / MEROPENEM + PHENYLBORONIC ACID MRP/MBO 0.125-8 / 0.032-2 10 MIC Tests
92168	ERTAPENEM / ERTAPENEM + PHENYLBORONIC ACID ETP/EBO 0.125-8 / 0.032-2 30 MIC Tests
921680	ERTAPENEM / ERTAPENEM + PHENYLBORONIC ACID ETP/EBO 0.125-8 / 0.032-2 100 MIC Tests
921681	ERTAPENEM / ERTAPENEM + PHENYLBORONIC ACID ETP/EBO 0.125-8 / 0.032-2 10 MIC Tests
92169	ERTAP/ERTAP+CLOXACILLIN ETP/ECX 0.125-8/0.032-2 30 MIC Tests
921690	ERTAP/ERTAP+CLOXACILLIN ETP/ECX 0.125-8/0.032-2 100 MIC Tests
921691	ERTAP/ERTAP+CLOXACILLIN ETP/ECX 0.125-8/0.032-2 10 MIC Tests

92170	ETHAMBUTOL EB 0.016-256 30 MIC Tests
921700	ETHAMBUTOL EB 0.016-256 100 MIC Tests
921701	ETHAMBUTOL EB 0.016-256 10 MIC Tests
92171	ISONIAZIDE IZ 0.016-256 30 MIC Tests
921710	ISONIAZIDE IZ 0.016-256 100 MIC Tests
921711	ISONIAZIDE IZ 0.016-256 10 MIC Tests
92172	ETHIONAMIDE ET 0.016-256 30 MIC Tests
921720	ETHIONAMIDE ET 0.016-256 100 MIC Tests
921721	ETHIONAMIDE ET 0.016-256 10 MIC Tests
92173	AZTREONAM ATM 0.064-1024 30 MIC Tests
921730	AZTREONAM ATM 0.064-1024 100 MIC Tests
921731	AZTREONAM ATM 0.064-1024 10 MIC Tests
92174	CEFAZOLIN KZ 0.016-256 30 MIC Tests
921740	CEFAZOLIN KZ 0.016-256 100 MIC Tests
921741	CEFAZOLIN KZ 0.016-256 10 MIC Tests
92180	AMOX*/CLAV 2 µg/mL AMC 0.016-256* 30 MIC Tests
921800	AMOX*/CLAV 2 µg/mL AMC 0.016-256* 100 MIC Tests
921801	AMOX*/CLAV 2 µg/mL AMC 0.016-256* 10 MIC Tests
92181	AMPIC*/SULB 4 µg/mL SAM 0.016-256* 30 MIC Tests
921810	AMPIC*/SULB 4 µg/mLSAM 0.016-256* 100 MIC Tests
921811	AMPIC*/SULB 4 µg/mL SAM 0.016-256* 10 MIC Tests
92182	MICAFUNGIN MYC 0,002-32 30 MIC Tests
921820	MICAFUNGIN MYC 0,002-32 100 MIC Tests
921821	MICAFUNGIN MYC 0,002-32 10 MIC Tests
92183	Ticarcillin TC 0.016-256 mg/L 30 MIC Tests
921830	Ticarcillin TC 0.016-256 mg/L 100 MIC Tests
921831	Ticarcillin TC 0.016-256 mg/L 10 MIC Tests
92184	Isavuconazole IVU 0.002-32 mg/L 30 MIC Tests
921840	Isavuconazole IVU 0.002-32 mg/L 100 MIC Tests
921841	Isavuconazole IVU 0.002-32 mg/L 10 MIC Tests
92200	Tiamulin TIA 0.002-32 30 MIC Tests
922000	Tiamulin TIA 0.002-32 100 MIC Tests
922001	Tiamulin TIA 0.002-32 10 MIC Tests
92201	TILMICOSIN TIL 0.002-32 30 MIC Tests
922010	TILMICOSIN TIL 0.002-32 100 MIC Tests
922011	TILMICOSIN TIL 0.002-32 10 MIC Tests
93001	EASY RID h-IgG
93002	EASY RID h-IgA
93003	EASY RID h-IgM
93004	EASY RID h-C3c
93005	EASY RID h-C4
93006	EASY RID h-Transferrin
93007	EASY RID h-Albumin
93008	EASY RID h-Apolipoprotein A1
93009	EASY RID h-Apolipoprotein B
93010	EASY RID h-Alfa 1 Acid Glicoprotein
93011	EASY RID h-Fibrinogen
93012	EASY RID h-Antitrombin III
93013	EASY RID h-Ig Light Chain K
93014	EASY RID h-Ig Light Chain Lambda
93015	Anti h-alfa 1 Antitrypsin
93016	Anti h-Ceruloplasmin
93018	Anti h-Haptoglobin
93104	Multiplate h-IgG/IgA/IgM
93106	MULTIPLATE h-C3c/C4
93110	MULTIPLATE h-Apo A1/Apo B
93115	MULTIPLATE h-Kappa Chain/Lambda Chain
93201	BENCE JONES TEST
940010	RID CONTROL SERUM
9501	OPTOCHINE OPT 100 Discs

9502	Bacitracin Test 100 Discs
9503	X FACTOR TEST 100 Discs
9504	V FACTOR TEST 100 Discs
9505	V+X FACTOR TEST 100 Discs
9508	METRONIDAZOLE TEST 100 Discs
9511	SULPHONAMIDE TEST 100 Discs
95200	ANAEROBES
95210	ENTEROCOCCI
95220	ENTEROBACTERIA 1
95230	ENTEROBACTERIA URINE
95240	ENTEROBACTERIA 2
95250	PSEUDOMONAS
95260	STAPH
95270	ACINETOBACTER
95280	YEASTS
95290	Strepto
95380	ENTEROBACTERIA
95390	PSEUDOMONAS ACINETOBACTER
95400	ENTEROCOCCI
95410	ANAEROBES
95420	STAPH/STREP
95430	ENTEROBACTERIA URINE
95440	ENTEROBACTERIA FROM URINE AND OTHER SAMPLE
95500	YEASTS
9555	MT-HAEMOPHILUS
9562	URIN-2
9563	MICE
9564	KGL I (Gram + ve) 1 x 100 Test
9565	KGL II (Gram - ve) 1 x 100 Test
9566	KGL III 100 Test
9567	MULTODISC A
9568	MULTODISC B
9569	MULTODISC C
9570	MULTODISC D
9571	MULTODISC A (100 Pz) (Tender106/2003)
9573	MULTODISC C (100 Pz) (Tender106/2003)
9574	MULTODISC D (100 Pz) (Tender106/2003)
9575	URINE RING (Tender238/2006)
9576	PSEUDOMONAS RING (Tender238/2006)
9577	GRAM NEGATIVE RING (Tender238/2006)
9578	GRAM POSITIVE RING (Tender238/2006)
96001	SALMONELLA TYPHI H 20 ml
96002	SALMONELLA TYPHI O 20 ml
96003	SALMONELLA PARATYPHI AH 20 ml
96004	SALMONELLA PARATYPHI AO 20 ml
96005	SALMONELLA PARATYPHI BH 20 ml
96006	SALMONELLA PARATYPHI BO 20 ml
96007	BRUCELLA TOTALE 20 ml
96008	BRUCELLA ABORTUS 20 ml
96009	SALMONELLA TYPHI TOTALE 20 ml CE
96010	SALMONELLA PARATYPHI A TOTALE 20 ml
96011	PROTEUS OX2 20 ml
96012	PROTEUS OXK 20 ml
96013	PROTEUS OX19 20 ml
96015	FEBRILE MULTITEST KIT
96016	STREP-CHECK KIT
96017	STAPH LATEX KIT
96018	SALMONELLA PARATYPHI B TOTALE 20 ml
96019	SALMONELLA PARATYPHI CH 20 ml
96020	SALMONELLA PARATYPHI CO 20 ml
96021	SALMONELLA PARATYPHI C TOTALE 20 ml
96022	BRUCELLA MELITENSIS 20 ml
96023	BRUCELLA SUIS 20 ml
96031	SALMONELLA TYPHI H SLIDE 5 ml
96032	SALMONELLA TYPHI O SLIDE 5 ml
96033	SALMONELLA TYPHI TOTALE 5 ml SLIDE
96034	SALMONELLA PARATYPHI AH SLIDE 5 ml
96035	SALMONELLA PARATYPHI AO 5 ml SLIDE
96036	SALMONELLA PARATYPHI A TOTALE 5ml SLIDE
96037	SALMONELLA PARATYPHI BH 5 ml SLIDE
96038	SALMONELLA PARATYPHI BO 5 ml SLIDE
96039	SALMONELLA PARATYPHI B TOTALE 5ml SLIDE
96040	SALMONELLA PARATYPHI CH 5 ml SLIDE
96041	SALMONELLA PARATYPHI CO 5 ml SLIDE
96042	SALMONELLA PARATYPHI C TOTALE 5 ml SLIDE
96043	BRUCELLA TOTALE SLIDE 5 ml SLIDE
96044	BRUCELLA ABORTUS 5 ml SLIDE
96045	BRUCELLA MELITENSIS SLIDE 5 ml
96046	BRUCELLA BENGAL ROSE SLIDE 5 ml
96047	PROTEUS OX2 5 ml SLIDE
96048	PROTEUS OX19 5 ml SLIDE
96049	PROTEUS OXK 5 ml SLIDE
96093	CONTROLLO NEGATIVO/NEGATIVE CONTROL 0.5ml
96096	POSITIVE CONTROL FOR SALMONELLA 0.5ml
96097	POSITIVE CONTROL FOR PROTEUS 0.5ml
96098	POSITIVE CONTROL FOR BRUCELLA 0.5ml
96142	Legionella Latex Kit
96143	CAMPYLOBACTER LATEX KIT
96144	CLOSTRIDIUM DIFFICILE LATEX KIT
96148	SHIGELLA ANTISERUM
96150	E. COLI O157 LATEX KIT
96151	SALMONELLA LATEX KIT
96153	STREPTO B LATEX KIT
96154	STREPTO A LATEX KIT
96155	BENCE JONES LATEX TEST
96316	Clostridium difficile GDH Card
96317	Clostridium Difficile Toxin A+B Card
96318	Giardia Card
96319	Listeria Monocytogenes Card
96320	Salmonella Ag Card
96321	O157 E.coli Card
96401	ONE STEP AMP DRMG SCREEN 20 CARDS
96404	ONE STEP COC DRMG SCREEN
96405	ONE STEP THC DRMG SCREEN
96406	ONE STEP M-AMP DRMG SCREEN 20 CARDS
96411	ONE STEP BRUPRENORPHINE DRMG SCREEN 20 CARDS
96415/20	FECAL OCCULT BLOOD CARD
96418	STREPTO A CARD 30 CARDS
96441	Gonorrea Ag Card
96442	Gardnerella Vaginalis Card
96443	Trichomonas Vaginalis Card
96444	B.J. Free Kappa/Lambda Dipstick
96455	H.PYLORI CARD 20 CARD
96460	HCG URINE/SERUM CARD 50 CARD
96461	HCG URINE/SERUM CARD 100 CARD
96462	MICROALBUMIN CARD URINE 20 Cards
96465	AFP -ALFA FETO CARD 20 CARDS
96468	TUBERCOLOSI CARD 20 CARDS
96480	IgE TOTAL CARD
96485	CEA CARD 20 Cards

96487	MYOGLOBIN
96488	TROPONIN 20 CARDS
96490	FERRITIN CARD
96495	SIFILIDE CARD 20 CARDS
96498	IM MONONUCLEOSIS INFECTION 20 CARDS
96590	URINE STRIP
96900	GIOTTO READER
96909	BIOMIC V3
96914	BIOMIC V3 AST
96915	BIOMIC V3 ID
96916	BIOMIC V3 CC
96919	AST Software
96931	ID Software
96932	CC Software
96933	Micropiastre 96 pozzetti Software

97800	ROTASTICK ONE STEP KIT 20 Tests
97801	RSV STICK ONE STEP 20 Tests
97802	ROTA/ADENO COMBI STICK ONE STEP 20 Tests
97803	H.PYLORI FECAL Ag ONE STEP 20 Tests
97805	STREP B STICK ONE STEP ASSAY 20 Tests
97807	ADENOSTICK ONE STEP ASSAY 20 Tests
9999	Blank Discs
99003	KPC&MBL disc kit (acc. to EUCAST)
99004	ESBL disc kit (acc. to EUCAST)
99005	ESBL disc kit (acc. to CLSI)
99006	ESBL (Chromos. Ind. AmpC) disc kit (acc. to EUCAST)
99007	KPC&MBL&OXA-48 disc kit (acc. to EUCAST)
99008	ESBL+AmpC screen disc kit
99009	AmpC disc kit

Direttore Tecnico/ Technical Director
Dr.Silvio Brocco

Italia

CERTIFICATO

Nr. 50 100 11497 Rev.005

SI ATTESTA CHE / *THIS IS TO CERTIFY THAT*

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

LIOFILCHEM S.r.l.

SEDE LEGALE:
REGISTERED OFFICE:

VIA SCOZIA - ZONA INDUSTRIALE
IT - 64026 ROSETO DEGLI ABRUZZI (TE)

SEDI OPERATIVE: **VEDI ALLEGATO 1** / *OPERATIONAL SITES:* ***SEE ANNEX 1***

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in-vitro: terreni di coltura per microbiologia, sistemi di identificazione e antibiogramma, strip per determinazione della Minima Concentrazione Inibente, dischetti antibiotici, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro (IAF 12, 29)

Design and development, production and sales of in-vitro diagnostic medical devices: culture media for microbiology, identification and susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, kits for plasma protein determination. Distribution of other in-vitro diagnostic medical devices (IAF 12, 29)

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Validità / *Validity*

Dal / From: **2022-02-11**

Al / To: **2025-02-10**

Data emissione / *Issuing Date*

2022-01-26

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2012-09-25

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2022-02-10
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2022-02-10*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

Italia

ALLEGATO 1 AL CERTIFICATO NR **50 100 11497 Rev.005**
ANNEX 1 *TO CERTIFICATE NO* ***50 100 11497 Rev.005***
pagina 1 di 1 / *page 1 of 1*

IL CERTIFICATO NR 50 100 11497 Rev.005 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
THE CERTIFICATE N *50 100 11497 Rev.005 COVERS ALSO THE FOLLOWING OFFICES:*

LIOFILCHEM S.r.l.

VIA SCOZIA - ZONA INDUSTRIALE IT - 64026 ROSETO DEGLI ABRUZZI (TE)

Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine

Production and sales of in-vitro diagnostic medical devices: dehydrated and ready-to-use culture media for microbiology

VIA URUGUAY IT - 64026 ROSETO DEGLI ABRUZZI (TE)

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in-vitro: terreni di coltura pronti per microbiologia, reagenti e supplementi, sistemi di identificazione e antibiogramma, strip per determinazione della Minima Concentrazione Inibente, dischetti antibiotici, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro. Progettazione e sviluppo e commercializzazione di terreni di coltura disidratati per microbiologia

Design and development, production and sales of in-vitro: diagnostic medical devices: ready-to-use culture media for microbiology, reagents and supplements, microbial identification and antimicrobial susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, plasma protein determination kits. Distribution of other in-vitro diagnostic medical devices. Design and development and distribution of dehydrated culture media for microbiology

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Validità /*Validity*

Dal / From: **2022-02-11**

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2022-01-26

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2012-09-25

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EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2022-02-10*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 071067 0006 Rev. 02

Holder of Certificate: **Liofilchem S.r.l.**
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALY

Certification Mark:

Scope of Certificate: **Design and development, production and sales of in-vitro diagnostic medical devices: culture media for microbiology, identification and susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, kits for plasma protein determination. Distribution of other in-vitro diagnostic medical devices.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 071067 0006 Rev. 02

Report No.: ITA 1775694

Valid from: 2021-12-19
Valid until: 2024-12-18

Date, 2021-12-10

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 071067 0006 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Liofilchem S.r.l.
Via Scozia, 64026 Roseto degli Abruzzi (TE), ITALY

Production and sales of in-vitro diagnostic medical devices: dehydrated and ready-to-use culture media for microbiology.

Liofilchem S.r.l.
Via Uruguay, 64026 Roseto degli Abruzzi (TE), ITALY

Design and development, production and sales of in-vitro:diagnostic medical devices: ready-to-use culture media for microbiology, reagents and supplements, microbial identification and antimicrobial susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, plasma protein determination kits. Distribution of other in-vitro diagnostic medical devices. Design and development and distribution of dehydrated culture media for microbiology.

/

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

№ 005032

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.03842

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «Агат-Мед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к разработке, производству и продаже медицинских изделий для in vitro диагностики: реагентов и наборов реагентов для клинической биохимии, а также калибраторов и контрольных материалов

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

РАЗРЕШЕНИЕ
на применение знака соответствия системы добровольной сертификации ГОСТ Р «EAC AUDIT»

Регистрационный номер № 04EAC1.CM.03842

ВЫДАНО НА ОСНОВАНИИ РЕШЕНИЯ О ВЫДАЧЕ СЕРТИФИКАТА СООТВЕТСТВИЯ СИСТЕМЫ МЕНЕДЖМЕНТА КАЧЕСТВА ИЗДЕЛИЙ МЕДИЦИНСКИХ

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

РАЗРЕШАЕТ

Применять знак соответствия системы добровольной сертификации «EAC AUDIT» на период действия сертификата соответствия № 04EAC1.CM.03842 в любой форме, исключающей возможность толкования его как знака соответствия качества продукции. Допускается использовать знак соответствия в рекламных буклетах, проспектах, брошюрах, плакатах, бланках организационно-распорядительной документации организации – держателя сертификата.

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27, этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-02

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Гладун Виталий Викторович

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
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СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
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ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
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ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27, этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-03

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: Курбатова (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

VACUTEST kima

www.vacutestkima.it

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE *"Dispositivi Medico-Diagnostici In Vitro" e s.m.i.*
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante / *manufacturer*: ***VACUTEST KIMA S.r.l. - articoli per laboratori analisi disposable labware***

indirizzo / *address*: ***Via dell'Industria, 12 35020 Arzergrande (PD) - Italia***

telefono / *phone* **+39-049-9720624** fax / *fax* **+39-049-9720182** posta elettronica / *e-mail* **info@vacutestkima.it**

identificazione dei prodotti / *product identification*:

Sistema di prelievo di sangue e altri liquidi biologici mediante provette con vuoto predeterminato in plastica "VACUTEST KIMA".

"VACUTEST KIMA" vacuum blood and biological liquids collection tubes in plastic.

nome commerciale / *brand name*: **"VACUTEST KIMA"**

classificazione dei prodotti / *product classification*: **dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.**
devices other then those mentioned in Annex II of the Directive 98/79/EC as amended

Si dichiara

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. *"Dispositivi Medico–Diagnostici In Vitro"*.
Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

Hereby we declare

under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".

All the supporting documents, as required by Annex III, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data / *place and date*: **Arzergrande, 01/01/2015**

firma / *signature*: **Assicuratore Qualità / Quality Manager**
Giovanni Chiarin

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**BOEN HEALTHCARE CO., LTD Unit 602, International Center, No.535, Shenxu Road, Suzhou, 215021, Jiangsu, China**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Centrifuge Tube**
der Klasse: / of class: / de la classe: / di classe:	**Common/Others IVD (Devices of NOT Annex II and NOT self-test)**

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II (IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l’inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d’évaluation de la conformité: / Procedura di valutazione della conformità:	**Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 / EG Annex III (expect point 6) of IVDD 98/79/EC Annexe III (sauf le point 6) de l'IVDD 98/79 / CE Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**
Registrier-Nr.: / Registration No.: / N°d’enregistrement: / Numero di registrazione:	
Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:	

CE

Suzhou, 2022.01.01

General Manager

Ort, Datum / Place, date / Lieu, date / Luogo, data

Name und Funktion / Name and function / Nom et fonction / Nome e funzione

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro. Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2020-10-30	2023-10-29

Settore IAF 14 - 29

SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

CERTIFICATO N° 505DM07

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Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro.

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L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione	Data di Prima Emissione ITALCERT	Data di Rinnovo	Data di Scadenza
First Issue Date	*First Issue Date ITALCERT*	*Renewal Date*	*Expiration Date*
2007-10-30	2011-10-30	2020-10-30	2023-10-29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
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Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

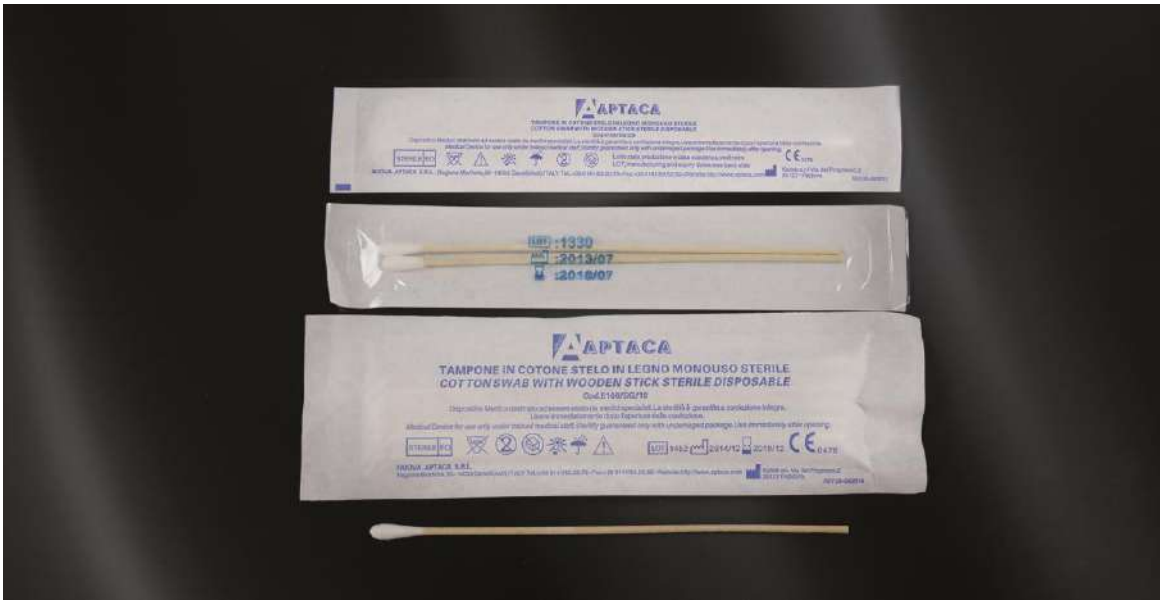
CERTIFIED COMPANY UNI EN ISO 9001 & UNI EN ISO 13485

SCHEDA DI SICUREZZA E TECNICA PRODOTTO
TECHNICAL AND SAFETY DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
18/02/2021

CODICE ARTICOLO:
ITEM CODE: **5100/SG/CS**

DESCRIZIONE / *DESCRIPTION*



Tampone sterile monouso per prelievi di cellule o l'assorbimento di essudati da piccole ferite. Puntale in 100% cotone (conforme alla Farmacopea Internazionale), privo di sostanze inibenti e di agenti sbiancanti fluorescenti. Stelo in legno non tossico e resistente agli sbalzi termici.
Il dispositivo ed il materiale di confezionamento sono prodotti con materiali atossici esenti da ftalati e lattice.
Sterili in confezione singola carta medicale/politene (peel-pack).

Disposable sterile swab for cell collection or absorption of exudates from small wounds. Tip 100% cotton (according to International Pharmacopoeia) free from inhibiting substances and fluorescent whitening agents. Wooden shafts non-toxic and resistant to thermal shock.
The device and the packaging material are produced with non-toxic materials phthalates-free and latex-free.
Sterile individually wrapped in medical paper/polythene (peel-pack).

Prodotto con marchio CE - conforme alla Direttiva 93/42/CE e al D.lgs 46 del 24/02/1997

CE *Marked product* - *manufactured in compliance with 93/42/CE Directive and D.lgs 46 dtd 24/02/1997*

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CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**STERILE / *STERILE***	*Microbilogical status*
Sterilizzazione	Ossido di Etilene / *Ethylene Oxide*	*Sterilization*
Materiale asta	Legno di betulla / *Wood birchen*	*Raw material – applicator stick*
Materiale puntale in fibra	100% Cotone / *100% Cotton* (International Pharmacopoeia)	*Raw material – fibre tip*
Lunghezza totale	150 ±4 mm	*Total length*
Lunghezza bulbo	15 ±4 mm	*Tip lenght*
Lunghezza asta	148 ±4 mm	*Stick lenght*
Diametro bulbo	5 ±1,5mm	*Tip diameter*
Diametro asta	2,2 ±0,15 mm	*Stick diameter*
Assorbimento acqua	0,15 g/pz	*Water absorption*
Validità del prodotto	5 Anni / *Years*	*Shelf life*

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella di "DISPOSITIVO MEDICO" (Classe I sterile - Invasivo temporaneo – regola 5) per prelievi di cellule o l'assorbimento di essudati da piccole ferite.
Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.
Classificazione Nazionale dei Dispositivi Medici (CND) > M010103 (TAMPONI DI OVATTA)
Repertorio Nazionale dei Dispositivi Medici (RDM) > 6787/R

Intended purpose is "MEDICAL DEVICE" (Class I sterile – Invasive Devices for transient use, rules 5) for cell collection or absorption of exudates from small wounds. ***For professional use only.***
National classification of medical devices (CND - For Italian law) > *M010103 (COTTON FLUFFS)*

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

Non avvicinare il dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare.
Keep out of flame or heat sources which might damage the product

Non utilizzare il prodotto scaduto o con la confezione aperta
Do not use after expiry date or if packing is opened

Non riutilizzare: Dispositivo monouso
Do not re-use: Disposable device

Non variare la destinazione d'uso
Do not vary the intended purpose of the product

Prodotto non adatto ai bambini
Keep out of reach of children

Conservare in luogo asciutto, Temperatura min -10°C max +50°C
Store in dry place, Temperature range: min -10°C max +50°C

Non usare con temperature esterna inferiore a 18°C
Do not use on external temperatures lower then 18°C

Smaltimento: utilizzare gli appositi D.P.I e smaltire secondo le normative vigenti
Disposal: use appropriate personal protective equipment and act according to applicable regulations

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.
Before use with particular substance check the resistance / compatibility chart on our catalogue

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PRECAUZIONI D'USO / *PRECAUTIONAL MEASURES*

- Osservare tecniche asettiche quando si utilizza il prodotto.
- Si deve supporre che ogni campione contenga microrganismi infettivi e si deve pertanto trattarlo con le dovute precauzioni. Dopo l'utilizzo, smaltire il tampone secondo le disposizioni del laboratorio relative al materiale infetto.
- Le istruzioni d'uso vanno seguite attentamente.
- Nel caso l'asta debba essere spezzata si consiglia l'uso di forbici sterili per una facile, sicura e pulita frattura.
- Nell'utilizzo del dispositivo la pressione esercitata durante il prelievo deve essere leggera in quanto il materiale dell'asta è frangibile.
- L'adesione della fibra all'asta è testata per prelievi istantanei; una durata prolungata del contatto fra tampone e zona del prelievo può causare la fuoriuscita della fibra.
- Se il tampone viene sottoposto ad un trattamento chimico o fisico a scopo sterilizzante o microbiostatico, la sua funzionalità potrebbe risultarne compromessa.

- Follow aseptic techniques when using the product.
- Each sample shall be assumed to be containing infectious micro-organisms and therefore it shall be treated with the necessary safety measures. After use the swabs shall be disposed of according to the laboratory provisions concerning infectious material.
- Strictly follow the user's instructions.
- Should the stick need to be broken, the use of sterile scissors is recommended for an easy, safe and clean cut.
- When using a device with plastic or wooden stick, the pressure applied during sampling shall be light since the stick material is breakable.
- The fibre adhesion to the stick is tested for instantaneous sampling; a longer contact between the swab and the sampling area might cause the fibre to come out.
- If the swab is submitted to a chemical or physical sterilizing or micro-biostatic process, its intended functioning could be compromised.

DETERIORAMENTO DEL PRODOTTO / *PRODUCT DETERIORATION*

Il contenuto delle unità non ancora aperte e non danneggiate è garantito sterile. Non utilizzarle se presentano tracce di danneggiamento, disidratazione o contaminazione.
Non usarle se già scadute.

The content of the unopened and undamaged units is guaranteed to be sterile. Do not use the units in case of damage, dehydration or contamination.
Do not use if the expiration date has passed.

IMBALLO / *PACKING*

Quantità (pz): *Quantity (pcs):*	1.000	Confezione interna (pz): *Internal packing (pcs):*	Singola *Individually*	QUANTITÀ MINIMA VENDIBILE *MINIMUM SALEABLE QUANTITY*	
Misura esterna scatola (cm): *External box dimensions (cm):*	20 x 20 x 24,5	Peso (Kg): *Weight (Kg):*	1,35	Volume (m^3): *Volume (m^3):*	0,013

SIMBOLI UTILIZZATI SULL'IMBALLO / *PACKING SYMBOLS*


Data di fabbricazione
Manufacturing date


Data di scadenza
Expiry date


Consultare i documenti accompagnatori
Please consult accompanying documents

Numero di lotto
Lot number


Monouso
Disposable

Sterilizzazione con Ossido di Etilene (EO)
Sterilization by Ethylene Oxide (EO)