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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).

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

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Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

Digitally signed by Ceaicovschi Tudor
Date: 2023.12.16 11:14:51 EET
Reason: MoldSign Signature
Location: Moldova

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

ISO 9001 -NF EN ISO 13485

ELITechGroup SEPPIM

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DECLARATION DE CONFORMITE CE

Nous, SEPPIM S.A.S., zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 1 «METABOLITES DIVERS », référencés dans la liste ci-jointe, 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.
Cette déclaration s'appuie sur le contenu de chaque dossier technique DOS-CE-XXXX.
(Voir liste ci-jointe).

Sées, le 08 Mars 2012

DECLARATION OF EC CONFORMITY

We, SEPPIM S.A.S., Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 1, "MISCELLANEOUS METABOLITES", such as listed hereto, 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.
This declaration is based upon the contents of each DOS-CE-XXXX technical file.
(See attached list).

Sées, March 8th, 2012

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, SEPPIM S.A.S, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 1 : "METABÓLICOS VARIOS ", referenciados en la lista adjunta, 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.
Esta declaración está documentada por su contenido de cada archivo técnico DOS-CE-XXXX
(Ver lista adjunta)

Sées, 8 de Marzo de 2012

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

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Président
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GROUPE 1 - METABOLITES DIVERS
GROUP 1 - MISCELLANEOUS METABOLITES
GRUPO 1 – METABÓLICOS VARIOS

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE
LACTATE	LACT-0100	DOS-CE-LACT
URIC ACID MONO SL	AUML-0420/0500/0700/ 0427/0507/0707/0250	DOS-CE-AUML
URIC ACID SL	AUSL-0400/0600/0250	DOS-CE-AUSL
URIC ACID	ACUR-0200/0400/0600	DOS-CE-ACUR
ALBUMIN	ALBU-0600/0700/0250	DOS-CE-ALBU
BILIRUBIN TOTAL & DIRECT 4+1	BITD-0600 BIDI-0600/0250 BITO-0600/0250	DOS-CE-BILI 4/1
CREATININE JAFFE	CRCO-0600/0700	DOS-CE-CRCO
CREATININE PAP SL	CRSL-0630/0250	DOS-CE-CRSL
IRON TIBC	FECA-0050	DOS-CE-TIBC
GLUCOSE PAP SL	GPSL-0490/0500/0700/ 0507/0707/0250/0455	DOS-CE-GPSL
GLUCOSE PAP	GLUP-0700/0800	DOS-CE-GLUP
GLUCOSE HK SL	GHSL-0600/0250	DOS-CE-GHSL
HEMOGLOBIN	HEMO-0400/0500	DOS-CE-HEMO
MICROPROTEIN	PRTP-0600/0250	DOS-CE-PRTP
MICROPROTEIN PLUS	PRTU-0600/0250	DOS-CE-PRTU
PHOSPHORUS	PHOS-0600/0230	DOS-CE-PHOS
TOTAL PROTEIN	PRTB-0600/0700/0250	DOS-CE-PRTB
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	DOS-CE-PROB
UREA UV SL	URSL-0400/0420/0500 0407/0427/0507/0250/0455	DOS-CE-URSL
UREA UV	URUV-0400/0500	DOS-CE-URUV

VG

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Société par actions simplifiée au Capital de 1 219 592.14 €
SIRET 318 365 228 00036 APE 2059Z
RC ALENCON 318 365 228

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DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 1 «METABOLITES DIVERS », référencés dans la liste ci-jointe, 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 là santé publique.

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon les normes ISO 9001 : 2008 et NF EN ISO 13485 : 2012. (Certification valable jusqu'au 27 juillet 2017).

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 1 "MISCELLANEOUS METABOLITES", such as listed hereto, 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.

This declaration is based on the contents of each DOS-CE-XXXX technical file and is supported by the certification of our quality system according to the standards ISO 9001 : 2008 and NF EN ISO 13485 : 2012 (Certification valid until July 27th , 2017).

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 1 "METABÓLICOS VARIOS ", referenciados en la lista adjunta, 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.

Esta declaración se basa en el contenido de cada DOS-CE-XXXX técnica y está respaldado por la certificación de nuestro sistema de calidad según las normas ISO 9001 : 2008 y EN NF ISO 13485 : 2012 (Certificación válida hasta el 27 de Julio 2017).

(Ver lista adjunta)

Sées, le 24 novembre 2014

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

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Françoise DEBIAIS,
Président
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Presidente

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GROUPE 1 - METABOLITES DIVERS
GROUP 1 - MISCELLANEOUS METABOLITES
GRUPO 1 – METABÓLICOS VARIOS

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE	Code GMDN/ GMDN Code/ Codigo GMDN
ALBUMIN	ALBU-0600/0700/0250	DOS-CE-ALBU	53597
BILIRUBIN TOTAL 4+1	BITO-0600/0250 BITD-0600	DOS-CE-BILI 4/1	53230
BILIRUBIN DIRECT 4+1	BIDI-0600/0250 BITD-0600		53232
CREATININE JAFFE	CRCO-0600/0700	DOS-CE-CRCO	53251
CREATININE PAP SL	CRSL-0630/0250	DOS-CE-CRSL	53250
IRON TIBC	FECA-0050	DOS-CE-TIBC	53904
GLUCOSE PAP SL	GPSL-0495/0500/0700/ 0507/0707/0250/0455/	DOS-CE-GPSL	53301
GLUCOSE PAP	GLUP-0700	DOS-CE-GLUP	53301
GLUCOSE HK SL	GHSL-0600/0250	DOS-CE-GHSL	53301
HEMOGLOBIN	HEMO-0400/0500	DOS-CE-HEMO	32430
LACTATE	LACT-0100	DOS-CE-LACT	53342
MICROPROTEIN PLUS	PRTU-0600/0250	DOS-CE-PRTU	53481
PHOSPHORUS	PHOS-0600/0230	DOS-CE-PHOS	30191
TOTAL PROTEIN	PRTB-0600/0700/0250	DOS-CE-PRTB	53985
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	DOS-CE-PROB	53985
URIC ACID MONO SL	AUML-0420/0500/0700/ 0427/0507/0707/0250	DOS-CE-AUML	53583
URIC ACID SL	AUSL-0400/0600/0250	DOS-CE-AUSL	53583
URIC ACID	ACUR-0200/0400/0600	DOS-CE-ACUR	53583
UREA UV SL	URSL-0400/0420/0500 0407/0427/0507/0250/0455	DOS-CE-URSL	53587
UREA UV	URUV-0400	DOS-CE-URUV	53587

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V.G.

ISO 9001 -NF EN ISO 13485

ELITechGroup SEPPIM

REAGENTS

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DECLARATION DE CONFORMITE CE

Nous, SEPPIM S.A.S., zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 2 « ENZYMES », référencés dans la liste ci-jointe, 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.
Cette déclaration s'appuie sur le contenu de chaque dossier technique DOS-CE-XXXX.
(Voir liste ci-jointe).

Sées, le 08 Mars 2012

DECLARATION OF EC CONFORMITY

We, SEPPIM S.A.S., Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 2, "ENZYMES", such as listed hereto, 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.
This declaration is based upon the contents of each DOS-CE-XXXX technical file.
(See attached list).

Sées, March 8th, 2012

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, SEPPIM S.A.S, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 2 : "ENZIMAS", referenciados en la lista adjunta, 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.
Esta declaración está documentada por su contenido de cada archivo técnico DOS-CE-XXXX
(Ver lista adjunta)

Sées, 8 de Marzo de 2012

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

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GROUPE 2 - ENZYMES
GROUP 2 – ENZYMES
GRUPO 2 – ENZIMAS

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE
ACID PHOSPHATASE	PACI-0030	DOS-CE-PACI
ALP (DEA) SL	PASL-0400/0420/0500/0230	DOS-CE-PASL
ALP (DEA)	PALC-0030/0200	DOS-CE-PALC
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	DOS-CE-ALSL 4+1
ALT /GPT	ALAT-0200/0400	DOS-CE-ALAT
AMYLASE SL	AMSL-0390/0395/0400/0230	DOS-CE-AMSL
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	DC-CE-ASSL 4+1
AST/GOT	ASAT-0200/0400	DOS-CE-ASAT
CHOLINESTERASE	CHES-0053	DOS-CE-CHES
CK NAC SL	CKSL-0410/0430/0230	DOS-CE-CKSL
CK-MB SL	CMSL-0410/0430/0230	DOS-CE-CMSL
CK NAC	CKNA-0030/0200	DOS-CE-CKNA
CK-MB	CKMB-0030	DOS-CE-CKMB
GAMMA GT SL	GASL-0400/0420/0500/0250	DOS-CE-GASL
GAMMA-GT SL PLUS	GISL-0400/0420/0500/0250	DOS-CE-GISL
GAMMA GT	GAGT-0030/0200	DOS-CE-GAGT
LDH-L SL	LLSL-0400/0420/0230	DOS-CE-LLSL
LDH-P	LDHP-0030	DOS-CE-LDHP

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DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 2 « ENZYMES », référencés dans la liste ci-jointe, 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.

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon les normes ISO 9001 : 2008 et NF EN ISO 13485 : 2012. (Certification valable jusqu'au 27 juillet 2017).

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 2, "ENZYMES", such as listed hereto, 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.

This declaration is based on the contents of each DOS-CE-XXXX technical file and is supported by the certification of our quality system according to the standards ISO 9001 : 2008 and NF EN ISO 13485 : 2012 (Certification valid until July 27th , 2017).

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 2 : "ENZIMAS", referenciados en la lista adjunta, 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.

Esta declaración se basa en el contenido de cada DOS-CE-XXXX técnica y está respaldado por la certificación de nuestro sistema de calidad según las normas ISO 9001 : 2008 y EN NF ISO 13485 : 2012 (Certificación válida hasta el 27 de Julio 2017).

(Ver lista adjunta)

Sées, le 24 Novembre 2014

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

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GROUPE 2 - ENZYMES
GROUP 2 – ENZYMES
GRUPO 2 – ENZIMAS

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	**REFERENCES/ REFERENCIAS**	**NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE**	**Code GMDN/ GMDN Code/ Codigo GMDN**
ALP (DEA) SL	PASL-0400/0420/0500/0230	DOS-CE-PASL	52928
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	DOS-CE-ALSL 4+1	52923
ALT /GPT	ALAT-0200/0400	DOS-CE-ALAT	52923
AMYLASE SL	AMSL-0390/0395/0400/0230	DOS-CE-AMSL	52940
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	DC-CE-ASSL 4+1	52954
AST/GOT	ASAT-0200/0400	DOS-CE-ASAT	52954
CHOLINESTERASE	CHES-0053	DOS-CE-CHES	51971
CK NAC SL	CKSL-0410/0430/0230	DOS-CE-CKSL	53003
CK-MB SL	CMSL-0410/0430/0230	DOS-CE-CMSL	52994
CK NAC	CKNA-0030/0200	DOS-CE-CKNA	53003
CK-MB	CKMB-0030	DOS-CE-CKMB	52994
GAMMA-GT SL PLUS	GISL-0400/0420/0500/0250	DOS-CE-GISL	53027
LDH-L SL	LLSL-0400/0420/0230	DOS-CE-LLSL	53072
LDH-P	LDHP-0030	DOS-CE-LDHP	53072

V.G.

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DECLARATION DE CONFORMITE CE

Nous, SEPPIM S.A.S., zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 3 «ELECTROLYTES/OLIGO-ELEMENTS», référencés dans la liste ci-jointe, 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.
Cette déclaration s'appuie sur le contenu de chaque dossier technique DOS-CE-XXXX.
(Voir liste ci-jointe).

Sées, le 13 Septembre 2010

DECLARATION OF EC CONFORMITY

We, SEPPIM S.A.S., Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 3, "ELECTROLYTES/TRACE-ELEMENTS", such as listed hereto, 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.
This declaration is based upon the contents of each DOS-CE-XXXX technical file.
(See attached list).

Sées, September 13th, 2010

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, SEPPIM S.A.S, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 3 : "ELECTROLITOS/OLIGO-ELEMENTOS", referenciados en la lista adjunta, 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.
Esta declaración está documentada por su contenido de cada archivo técnico DOS-CE-XXXX
(Ver lista adjunta)

Sées, 13 de Septiembre de 2010

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

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GROUPE 3 – ELECTROLYTES / OLIGO-ELEMENTS
GROUP 3 – ELECTROLYTES / TRACE-ELEMENTS
GRUPO 3 – ELECTROLITOS / OLIGO-ELEMENTOS

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE
CALCIUM ARSENAZO	CALA-0600/0250	DOS-CE-CALA
CALCIUM OCPC	CALO-0600	DOS-CE-CALO
CHLORIDE	CHLO-0600/0250	DOS-CE-CHLO
COPPER	CUIV-0050	DOS-CE-CUIV
IRON CHROMAZUROL	FECA-0600	DOS-CE-FECA
IRON FERROZINE	FEFR-0600/0250	DOS-CE-FEFR
MAGNESIUM CALMAGITE	MAGN-0600/0125	DOS-CE-MAGN

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DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 3 «ELECTROLYTES/OLIGO-ELEMENTS», référencés dans la liste ci-jointe, 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.

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon les normes ISO 9001 : 2008 et NF EN ISO 13485 : 2012. (Certification valable jusqu'au 27 juillet 2017).

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 3 "ELECTROLYTES/TRACE-ELEMENTS", such as listed hereto, 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.

This declaration is based on the contents of each DOS-CE-XXXX technical file and is supported by the certification of our quality system according to the standards ISO 9001 : 2008 and NF EN ISO 13485 : 2012 (Certification valid until July 27th , 2017).

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 3 "ELECTROLITOS/OLIGO-ELEMENTOS ", referenciados en la lista adjunta, 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.

Esta declaración se basa en el contenido de cada DOS-CE-XXXX técnica y está respaldado por la certificación de nuestro sistema de calidad según las normas ISO 9001 : 2008 y EN NF ISO 13485 : 2012 (Certificación válida hasta el 27 de Julio 2017).

(Ver lista adjunta)

Sées, le 24 Novembre 2014

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

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GROUPE 3 – ELECTROLYTES / OLIGO-ELEMENTS
GROUP 3 – ELECTROLYTES / TRACE-ELEMENTS
GRUPO 3 – ELECTROLITOS / OLIGO-ELEMENTOS

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	**REFERENCES/ REFERENCIAS**	**NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE**	**Code GMDN/ GMDN Code/ Codigo GMDN**
CALCIUM ARSENAZO	CALA-0600/0250	DOS-CE-CALA	45789
CHLORIDE	CHLO-0600/0250	DOS-CE-CHLO	60037
IRON CHROMAZUROL	FECA-0600	DOS-CE-FECA	54758
IRON FERROZINE	FEFR-0600/0250	DOS-CE-FEFR	54758
MAGNESIUM CALMAGITE	MAGN-0600/0125	DOS-CE-MAGN	46795

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DECLARATION DE CONFORMITE CE

Nous, SEPPIM S.A.S., zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 4 «LIPIDES », référencés dans la liste ci-jointe, 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.
Cette déclaration s'appuie sur le contenu de chaque dossier technique DOS-CE-XXXX.
(Voir liste ci-jointe).

Sées, le 08 Mars 2012

DECLARATION OF EC CONFORMITY

We, SEPPIM S.A.S., Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 4, "LIPIDS", such as listed hereto, 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.
This declaration is based upon the contents of each DOS-CE-XXXX technical file.
(See attached list).

Sées, March 8th, 2012

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, SEPPIM S.A.S, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 4 : "LÍPIDOS ", referenciados en la lista adjunta, 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.
Esta declaración está documentada por su contenido de cada archivo técnico DOS-CE-XXXX
(Ver lista adjunta)

Sées, 8 de Marzo de 2012

Valérie GOURDON,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
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GROUPE 4 – LIPIDES
GROUP 4 – LIPIDS
GRUPO 4 – LÍPIDOS

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE
CHOLESTEROL SL	CHSL-0490/0500/0700 0507/0707/0250/0455	DOS-CE-CHSL
CHOLESTEROL	CHOL-0220/0420/0720	DOS-CE-CHOL
HDL CHOLESTEROL	HDLC-0060	DOS-CE-HDLC
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	DOS-CE-HDLL
CHOLESTEROL LDL SL 2G	LDLL-0230/0380	DOS-CE-LDLL
TRIGLYCERIDES MONO SL NEW	TGML-0425/0515/0700 0427/0517/0707	DOS-CE-TGMLN
TRIGLYCERIDES SL	TGML-0250/0455	DOS-CE-TGMLN
TRIGLYCERIDES	TRIG-0200/0400	DOS-CE-TRIG

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DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 4 «LIPIDES », référencés dans la liste ci-jointe, 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.

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon les normes ISO 9001 : 2008 et NF EN ISO 13485 : 2012. (Certification valable jusqu'au 27 juillet 2017).

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 4 "LIPIDS", such as listed hereto, 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.

This declaration is based on the contents of each DOS-CE-XXXX technical file and is supported by the certification of our quality system according to the standards ISO 9001 : 2008 and NF EN ISO 13485 : 2012 (Certification valid until July 27th , 2017).

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 4 "LÍPIDOS ", referenciados en la lista adjunta, 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.

Esta declaración se basa en el contenido de cada DOS-CE-XXXX técnica y está respaldado por la certificación de nuestro sistema de calidad según las normas ISO 9001 : 2008 y EN NF ISO 13485 : 2012 (Certificación válida hasta el 27 de Julio 2017).

(Ver lista adjunta)

Sées, le 15 septembre 2014

Valérie GOURDON,
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Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

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GROUPE 4 – LIPIDES
GROUP 4 – LIPIDS
GRUPO 4 – LÍPIDOS

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	**REFERENCES/ REFERENCIAS**	**NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE**	**Code GMDN/ GMDN Code/ Codigo GMDN**
CHOLESTEROL SL	CHSL-0495/0500/0700/ 0507/0707/0250/0455	DOS-CE-CHSL	53359
CHOLESTEROL	CHOL-0220/0420/0720	DOS-CE-CHOL	53359
HDL CHOLESTEROL	HDLC-0060	DOS-CE-HDLC	53391
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	DOS-CE-HDLL	53391
CHOLESTEROL LDL SL 2G	LDLL-0230/0380/0390	DOS-CE-LDLL	53395
TRIGLYCERIDES MONO SL NEW	TGML-425/0495/0515/ 0700/0427/0517/0707	DOS-CE-TGMLN	53460
TRIGLYCERIDES SL	TGML-0250/0455	DOS-CE-TGMLN	53460
TRIGLYCERIDES	TRIG-0200/0400	DOS-CE-TRIG	53460

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DECLARATION DE CONFORMITE CE

Nous, SEPPIM S.A.S., zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les dispositifs appartenant au groupe 5 «CONTRÔLES/ CALIBRANTS/ STANDARDS », référencés dans la liste ci-jointe, 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.
Cette déclaration s'appuie sur le contenu de chaque dossier technique DOS-CE-XXXX.
(Voir liste ci-jointe).

Sées, le 08 Mars 2012

DECLARATION OF EC CONFORMITY

We, SEPPIM S.A.S., Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the devices belonging to Group 5, "CONTROLS/ CALIBRATORS/ STANDARDS", such as listed hereto, 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.
This declaration is based upon the contents of each DOS-CE-XXXX technical file.
(See attached list).

Sées, March 8th, 2012

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, SEPPIM S.A.S, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los dispositivos pertenecientes al grupo 5 : "CONTROLES/ CALIBRADORES/ ESTÁNDARES", referenciados en la lista adjunta, 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.
Esta declaración está documentada por su contenido de cada archivo técnico DOS-CE-XXXX
(Ver lista adjunta)

Sées, 8 de Marzo de 2012

Valérie GOURDON,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
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GROUPE 5 – CONTROLES/CALIBRANTS/STANDARDS
GROUP 5 – CONTROLS/CALIBRATORS/STANDARDS
GRUPO 5 – CONTROLES/CALIBRADORES/ESTÁNDARES

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE
CK-MB CONTROL	CKMB-0900	DOS-CE-CKMB-CT
ELICAL 2	CALI-0550	DOS-CE-CALI2
ELITROL I	CONT-0060	DOS-CE-ELIT I
ELITROL II	CONT-0160	DOS-CE-ELIT II
ISE CONTROL I	ISCT-0046	DOS-CE-ISCT
ISE CONTROL II	ISCT-0047	
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	DOS-CE-HDLL-CAL
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	DOS-CE-LDLL-CAL
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	DOS-CE-CHOL200
CREATININE Standard 2 mg/dL	CREN-0055	DOS-CE-CREN2
GLUCOSE Standard 100 mg/dL	GLUP-0055	DOS-CE-GLUP100
MICROPROTEIN Standard 20 mg/dL	PRTP-0020	DOS-CE-PRTP20
MICROPROTEIN Standard 100 mg/dL	PRTP-0022	DOS-CE-PRTP100
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	DOS-CE-PRTU100
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	DOS-CE-TRIG200
UREA Standard 50 mg/dL	URUV-0055	DOS-CE-URUV50
URIC ACID Standard 6 mg/dL	ACUR-0055	DOS-CE-ACUR6

VG

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SIRET : 318 365 228 00036

Société par actions simplifiée au Capital de 1 219 592.14 €
SIRET 318 365 228 00036 APE 2059Z
RC ALENCON 318 365 228

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Fax : +33 (0)2 33 28 77 51
www.elitechgroup.com

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 5 «CONTRÔLES/ CALIBRANTS/ STANDARDS », référencés dans la liste ci-jointe, 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.

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon les normes ISO 9001 : 2008 et NF EN ISO 13485 : 2012. (Certification valable jusqu'au 27 juillet 2017).

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 5, "CONTROLS/ CALIBRATORS/ STANDARDS", such as listed hereto, 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.

This declaration is based on the contents of each DOS-CE-XXXX technical file and is supported by the certification of our quality system according to the standards ISO 9001 : 2008 and NF EN ISO 13485 : 2012 (Certification valid until July 27th , 2017).

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 5 "CONTROLES/ CALIBRADORES/ ESTÁNDARES", referenciados en la lista adjunta, 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.

Esta declaración se basa en el contenido de cada DOS-CE-XXXX técnica y está respaldado por la certificación de nuestro sistema de calidad según las normas ISO 9001 : 2008 y EN NF ISO 13485 : 2012 (Certificación válida hasta el 27 de Julio 2017).

(Ver lista adjunta)

Sées, le 15 septembre 2014

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

Françoise DEBIAIS,
Président
President
Presidente

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GROUPE 5 – CONTROLES/CALIBRANTS/STANDARDS
GROUP 5 – CONTROLS/CALIBRATORS/STANDARDS
GRUPO 5 – CONTROLES/CALIBRADORES/ESTÁNDARES

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	**REFERENCES/ REFERENCIAS**	**NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE**	**Code GMDN/ GMDN Code/ Codigo GMDN**
CK-MB CONTROL	CKMB-0900	DOS-CE-CKMB-CT	44693
ELICAL 2	CALI-0550	DOS-CE-CALI2	47868
ELITROL I	CONT-0060	DOS-CE-ELIT I	47869
ELITROL II	CONT-0160	DOS-CE-ELIT II	47869
ISE CONTROL I	ISCT-0046	DOS-CE-ISCT	47869
ISE CONTROL II	ISCT-0047		47869
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	DOS-CE-HDLL-CAL	44696
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	DOS-CE-LDLL-CAL	41728
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	DOS-CE-CHOL200	44698
CREATININE Standard 2 mg/dL	CREN-0055	DOS-CE-CREN2	44700
GLUCOSE Standard 100 mg/dL	GLUP-0055	DOS-CE-GLUP100	41818
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	DOS-CE-PRTU100	53482
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	DOS-CE-TRIG200	44702
UREA Standard 50 mg/dL	URUV-0055	DOS-CE-URUV50	53588
URIC ACID Standard 6 mg/dL	ACUR-0055	DOS-CE-ACUR6	44704

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ISO 9001 -NF EN ISO 13485

ELITechGroup
SEPPIM
REAGENTS

Zone Industrielle – 61500 SEES – France
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DECLARATION DE CONFORMITE CE

Nous, SEPPIM S.A.S., zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 10 «PROTEINES SPECIFIQUES », référencés dans la liste ci-jointe, 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.
Cette déclaration s'appuie sur le contenu de chaque dossier technique DOS-CE-XXXX.
(Voir liste ci-jointe).

Sées, le 13 Janvier 2011

DECLARATION OF EC CONFORMITY

We, SEPPIM S.A.S., Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 10, "SPECIFIC PROTEINS", such as listed hereto, 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.
This declaration is based upon the contents of each DOS-CE-XXXX technical file.
(See attached list).

Sées, January 13th, 2011

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, SEPPIM S.A.S, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los dispositivos pertenecientes al grupo 10 : " PROTÉINAS ESPÉCIFICAS ", referenciados en la lista adjunta, 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.
Esta declaración está documentada por su contenido de cada archivo técnico DOS-CE-XXXX
(Ver lista adjunta)

Sées, 13 de Enero de 2011

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

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Françoise DEBIAIS,
Président
President
Presidente

ISO 9001 -NF EN ISO 13485

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GROUPE 10 – PROTEINES SPECIFIQUES / GROUP 10 – SPECIFIC PROTEINS
GRUPO 10 - PROTÉINAS ESPÉCIFICAS

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE
CRP IP	ICRP-0400	DOS-CE-CRP IP
CRP IP CALIBRATOR H	ICRP-0042	DOS-CE-CRPCAL
CRP IP CALIBRATOR SET	ICRP-0043	DOS-CE-CRPCAL
CRP IP CONTROL I	ICRP-0046	DOS-CE-CRPCON
CRP IP CONTROL II	ICRP-0047	DOS-CE-CRPCON
APO A1 IP	IAPA-0400	DOS-CE-APA
APO B IP	IAPB-0400	DOS-CE-APB
APO A1/B IP CALIBRATOR H	IAPO-0042	DOS-CE-APOCalH
APO A1/B IP CONTROL	IAPO-0048	DOS-CE-APOCon
TRANSFERRIN IP	ITRF-0400	DOS-CE TRF
PROTEIN IP CALIBRATOR H	IPRO-0041/0042	DOS-CE PROCAL
PROTEIN IP CALIBRATOR SET	IPRO-0043	DOS-CE PROCAL
PROTEIN IP CONTROL	IPRO-0045/0048	DOS-CE PROCON
µALBUMIN IP	IMAL-0400	DOS-CE-MAL
µALBUMIN IP CALIBRATOR H	IMAL-0042	DOS-CE-MALCal
µALBUMIN IP CALIBRATOR SET	IMAL-0043	DOS-CE-MALCal
µALBUMIN IP CONTROL I	IMAL-0046	DOS-CE-MALCon
µALBUMIN IP CONTROL II	IMAL-0047	DOS-CE-MALCon
IgA IP	IIGA-0400	DOS-CE-IIGA
IgG IP	IIGG-0400	DOS-CE-IIGG
IgM IP	IIGM-0400	DOS-CE-IIGM
HAPTOGLOBIN IP	IHAP-0400	DOS-CE-IHAP
OROSOMUCOID IP	IORO-0400	DOS-CE-IORO
PREALBUMIN IP	IPAL-0400	DOS-CE-IPAL
HbA1c	HBAC-0240	DOS-CE-HBAC
HbA1c CALIBRATOR SET	HBAC-0043	DOS-CE-HBAC
HbA1c CONTROL L + H	HBAC-0049	DOS-CE-HBAC
HbA1c CONTROL 80	HBAC-0050	DOS-CE-HBAC80

VG

Société par actions simplifiée au Capital de 1 219.592.14 €
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RC ALENCON 318 365 228

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DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 10 «PROTEINES SPECIFIQUES », référencés dans la liste ci-jointe, 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.

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon les normes ISO 9001 : 2008 et NF EN ISO 13485 : 2012. (Certification valable jusqu'au 27 juillet 2017).

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 10, "SPECIFIC PROTEINS", such as listed hereto, 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.

This declaration is based on the contents of each DOS-CE-XXXX technical file and is supported by the certification of our quality system according to the standards ISO 9001 : 2008 and NF EN ISO 13485 : 2012 (Certification valid until July 27th , 2017).

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 10 : " PROTÉINAS ESPÉCIFICAS" referenciados en la lista adjunta, 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.

Esta declaración se basa en el contenido de cada DOS-CE-XXXX técnica y está respaldado por la certificación de nuestro sistema de calidad según las normas ISO 9001 : 2008 y EN NF ISO 13485 : 2012 (Certificación válida hasta el 27 de Julio 2017).

(Ver lista adjunta)

Sées, le 24 novembre 2014

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

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GROUPE 10 – PROTEINES SPECIFIQUES
GROUP 10 – SPECIFIC PROTEINS
GRUPO 10 - PROTÉINAS ESPÉCIFICAS

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE	Code GMDN/ GMDN Code/ Codigo GMDN
CRP IP	ICRP-0400	DOS-CE-CRP IP	53705
CRP IP CALIBRATOR H	ICRP-0042	DOS-CE-CRPCAL	41838
CRP IP CALIBRATOR SET	ICRP-0043		41838
CRP IP CONTROL I	ICRP-0046	DOS-CE-CRPCON	41839
CRP IP CONTROL II	ICRP-0047		41839
APO A1 IP	IAPA-0400	DOS-CE-APA	53443
APO B IP	IAPB-0400	DOS-CE-APB	53447
APO A1/B IP CALIBRATOR H	IAPO-0042	DOS-CE-APOCalH	41809/41813
APO A1/B IP CONTROL	IAPO-0048	DOS-CE-APOCon	41808/41812
TRANSFERRIN IP	ITRF-0400	DOS-CE TRF	30253
PROTEIN IP CALIBRATOR SET	IPRO-0043	DOS-CE PROCAL	53593
PROTEIN IP CONTROL	IPRO-0045/0048	DOS-CE PROCON	30506
µALBUMIN IP	IMAL-0400	DOS-CE-MAL	53475
µALBUMIN IP CALIBRATOR H	IMAL-0042	DOS-CE-MALCal	53477
µALBUMIN IP CALIBRATOR SET	IMAL-0043		53477
µALBUMIN IP CONTROL I	IMAL-0046	DOS-CE-MALCon	53478
µALBUMIN IP CONTROL II	IMAL-0047		53478
IgA IP	IIGA-0400	DOS-CE-IIGA	53760
IgG IP	IIGG-0400	DOS-CE-IIGG	53787
IgM IP	IIGM-0400	DOS-CE-IIGM	53795
HAPTOGLOBIN IP	IHAP-0400	DOS-CE-IHAP	53737
OROSOMUCOID IP	IORO-0400	DOS-CE-IORO	53606
PREALBUMIN IP	IPAL-0400	DOS-CE-IPAL	53957
HbA1c	HBAC-0240	DOS-CE-HBAC	30168
HbA1c CALIBRATOR SET	HBAC-0043		53315
HbA1c CONTROL L + H	HBAC-0049		44435
HbA1c CONTROL 80	HBAC-0050	DOS-CE-HBAC80	44435

V.G.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ELITechGroup Inc.
370 West 1700 South
Logan
Utah
84321
USA

Facility ID Number: F000174

Holds Certificate No: **MDSAP 689350**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, manufacture, distribution and servicing of automated slide stainers, cytocentrifuges, cystic fibrosis sweat testing systems, and osmometers, and proprietary standards, controls disposables and reagents for use with these types of equipment. Manufacture and distribution of controls, standards, consumables, accessories and supplies for in vitro diagnostic systems, laboratory equipment, and erythrocyte sedimentation rate test systems.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-03-28 Effective Date: 2022-01-11 Expiry Date: 2025-01-10

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

Abbott

Declaration of Conformity

Certificate Identification: SC-08H59

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08H59-01	55866	CELL-DYN 26 Plus Control, Full Pack	**Self-declared**
08H59-02	55866	CELL-DYN 26 Plus Control, Half Pack	**Self-declared**

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
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:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	18 June 2015	Date of Approval:	30 June 2015
Date Issued:	JUN 30 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V5 February 26, 2015	Effective (Date or Lot Number):	JUL 06 2015

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074RUH0380WZ
Basic UDI-DI Name: CELL-DYN Ruby CN-FREE HGB/NOC LYSE
Risk Class: **Class A**

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
03H80-02	CELL-DYN Ruby CN-FREE HGB/NOC LYSE	61165	W010301199

Manufacturer (Name and Address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Manufacturer SRN	TBD
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)	ThermoFisher 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. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: Cheryl Nowlan
Function: Site QA, Director Quality Assurance
Signature: Cheryl Nowlan
Date of Approval: 19 APR 2023

Full Name: Katie Bessette
Function: Director Regulatory Affairs
Signature: Katie Bessett
Date of Approval: 19-APR-2023

Signed for, and on behalf of: Abbott Laboratories, Abbott Park, USA

Date Issued: APR 19 2023
Supersedes: March 28, 2023

Place Issued: Santa Clara, CA USA
Effective (Date or Lot Number): APR 19 2023

Abbott

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

Abbott

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 (Ονομα 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

Abbott

EN	Authorized Representative (Name and Address)	Authorized Representative SRN	Produced by (Site of Manufacture) (Name and Address)	Conformity Assessment Procedure
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)	Процедура за оценка на съответствието
CS	Zplnomocněný zástupce (název a adresa)	Jedinė registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)	Postup posuzování shody
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fremstillingssted) (navn og adresse)	Overensstemmelsesvurderingsprocedure
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)	Konformitätsbewertungsverfahren
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Ονομασία και Διεύθυνση)	Διαδικασία αξιολόγησης συμμόρφωσης
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)	Procedimiento de evaluación de la conformidad
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootja (tootmiskoht) (nimi ja aadress)	Vastavushindamismenetlus
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)	Procédure d'évaluation de la conformité
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)	Postupak ocjenjivanja sukladnosti
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)	Megfelelőségértékelési eljárás
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)	Procedura di valutazione della conformità
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)	Atbilstības novērtēšanas procedūra
LT	Įgaliotasis atstovas (pavadinimas ir adresas)	Įgaliotojo atstovo unikalusis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)	Atitikties vertinimo procedūra
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)	Framgangsmåte for samsvarsvurdering
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)	Procedura oceny zgodności
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)	Procedimento de avaliação da conformidade
RO	Reprezentant autorizat (nume şi adresă)	SRN reprezentant autorizat	Produs de către (locaţie producţie) (nume şi adresă)	Procedură de evaluare a conformităţii
SK	Autorizovaný zástupca (názov a adresa)	Jedinė registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)	Postup posudzovania zhody
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)	Förfarande för bedömning av överensstämmelse
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)	Uygunluk Değerlendirme Prosedürü

Abbott

EN	Annex II and III	Full Name
BG	Приложение II и III	Пълно наименование
CS	Příloha II a III	Celý název
DA	Bilag II og III	Fulde navn
DE	Anhang II und III	Vollständiger Name
EL	Παράρτημα II και III	Πλήρης ονομασία
ES	Anexos II y III	Nombre completo
ET	II ja III lisa	Täisnimi
FR	Annexes II et III	Nom complet
HR	Prilog II. i III.	Puni naziv
HU	II. és III. melléklet	Teljes név
IT	Allegati II e III	Nome completo
LV	II un III pielikums	Pilns nosaukums
LT	II ir III priedai	Vardas ir pavardė
NO	Vedlegg II og III	Fullt navn
PL	Załącznik II oraz III	Imię i nazwisko
PT	Anexo II e III	Nome completo
RO	Anexa II şi III	Numele complet
SK	Príloha II a III	Celý názov
SV	Bilaga II och III	Fullständigt namn
TR	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	Funcţia	Semnat pentru şi 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

Abbott

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)

Abbott

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. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**
BG	Ние, долуподписаните, с настоящото декларираме, че горесписаното(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. Тази декларация е направена в съответствие с Приложение IV на Регламента за IVD 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. Toto prohlášení je v souladu s Přílohou IV nařízení IVD 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. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV 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. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung 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. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD 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*. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD 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. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale ning selle väljastamise eest vastutab ainult tootja.
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*. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV 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. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD 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 (IVD rendelet) vonatkozó rendelkezéseinek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.
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*. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD 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. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV 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. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV 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. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen 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. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR 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*. Esta declaração é feita em conformidade com o anexo IV do Regulamento IVD 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. Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpísaní, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) 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. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD 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. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen 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 beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altındadır.

End of form

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074RUH0852XM
Basic UDI-DI Name: CELL-DYN Ruby WBC Lyse
Risk Class: **Class A**

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
08H52-01	CELL-DYN Ruby WBC Lyse	61165	W0103010105

Manufacturer (Name and Address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Manufacturer SRN	TBD
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)	ThermoFisher 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. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: Cheryl Nowlan
Function: Site QA, Director Quality Assurance
Signature: Cheryl Nowlan
Date of Approval: 28 MAR 2023

Full Name: Katie Bessette
Function: Director Regulatory Affairs
Signature: Kat Bessett
Date of Approval: 28-MAR-2023

Signed for, and on behalf of: Abbott Laboratories, Abbott Park, USA

Date Issued: MAR 28 2023
Supersedes: Oct 11, 2022

Place Issued: Santa Clara, CA USA
Effective (Date or Lot Number): MAR 28 2023

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 şi cod dimensiune	Denumirea produsului şi 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)	Conformity Assessment Procedure
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)	Процедура за оценка на съответствието
CS	Zplnomocněný zástupce (název a adresa)	Jediné registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)	Postup posuzování shody
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fremstillingssted) (navn og adresse)	Overensstemmelsesvurderingsprocedure
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)	Konformitätsbewertungsverfahren
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Ονομασία και Διεύθυνση)	Διαδικασία αξιολόγησης συμμόρφωσης
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)	Procedimiento de evaluación de la conformidad
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootja (tootmiskoht) (nimi ja aadress)	Vastavushindamismenetlus
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)	Procédure d'évaluation de la conformité
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)	Postupak ocjenjivanja sukladnosti
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)	Megfelelőségértékelési eljárás
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)	Procedura di valutazione della conformità
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)	Atbilstības novērtēšanas procedūra
LT	Įgaliotasis atstovas (pavadinimas ir adresas)	Įgaliotojo atstovo unikalusis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)	Atitikties vertinimo procedūra
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)	Framgangsmåte for samsvarsvurdering
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)	Procedura oceny zgodności
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)	Procedimento de avaliação da conformidade
RO	Reprezentant autorizat (nume și adresă)	SRN reprezentant autorizat	Produs de către (locație producție) (nume și adresă)	Procedură de evaluare a conformității
SK	Autorizovaný zástupca (názov a adresa)	Jediné registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)	Postup posudzovania zhody
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)	Förfarande för bedömning av överensstämmelse
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)	Uygunluk Değerlendirme Prosedürü

EN	Annex II and III	Full Name
BG	Приложение II и III	Пълно наименование
CS	Příloha II a III	Celý název
DA	Bilag II og III	Fulde navn
DE	Anhang II und III	Vollständiger Name
EL	Παράρτημα II και III	Πλήρης ονομασία
ES	Anexos II y III	Nombre completo
ET	II ja III lisa	Täisnimi
FR	Annexes II et III	Nom complet
HR	Prilog II. i III.	Puni naziv
HU	II. és III. melléklet	Teljes név
IT	Allegati II e III	Nome completo
LV	II un III pielikums	Pilns nosaukums
LT	II ir III priedai	Vardas ir pavardė
NO	Vedlegg II og III	Fullt navn
PL	Załącznik II oraz III	Imię i nazwisko
PT	Anexo II e III	Nome completo
RO	Anexa II şi III	Numele complet
SK	Príloha II a III	Celý názov
SV	Bilaga II och III	Fullständigt namn
TR	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	Funcţia	Semnat pentru şi 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. This declaration is made in accordance with Annex IV of the IVD Regulation 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. Тази декларация е направена в съответствие с Приложение IV на Регламента за IVD 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. Toto prohlášení je v souladu s Přílohou IV nařízení IVD 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. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV 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. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung 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. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD 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*. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD 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. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale ning selle väljastamise eest vastutab ainult tootja.
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*. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV 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. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD 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 (IVD rendelet) vonatkozó rendelkezéseinek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.
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*. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD 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. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV 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. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV 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. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen 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. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR 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*. Esta declaração é feita em conformidade com o anexo IV do Regulamento IVD 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. Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpísaní, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) 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. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD 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. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen 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 beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altındadır.

End of form

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
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ИНН 7717616798 ОГРН 1087746489060
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№ 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

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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»

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(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

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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

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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

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

М.П.

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NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com - www.aptaca.com - www.vacucheck.com
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 -R.E.A. MB 1167248

CERTIFIED COMPANY UNI EN ISO 9001:2008 & UNI CEI EN ISO 13485:2012

DICHIARAZIONE DI CONFORMITA' CE

CE *DECLARATION OF CONFORMITY*

La sottoscritta Nuova Aptaca s.r.l.
The undersigned Nuova Aptaca s.r.l.

DICHIARA
DECLARES

Che il dispositivo medico diagnostico in vitro di seguito descritto:
That in vitro diagnostic medical devices described as follows:

CONTENITORI PER CAMPIONI BIOLOGICI

SPECIMEN CONTAINERS

PRODOTTI NON STERILI – *NOT STERILE PRODUCTS*

(i cui codici di dettaglio sono riportati nell'allegato 1)
(which detailed codes are reported in Annex 1)

> **Sono conformi ai requisiti essenziali di cui all'allegato I della direttiva 98/79/CE del 27 ottobre 1998 recepita con il D.Lgs 332 del 08/09/2000.**
Are manufactured in compliance with essential requirements of Annex 1 of the 98/79/CE Directive dated 27Th October 1998 put into force by D.Lgs. 332 dated 08/09/2000.

> **I Dispositivi di cui all'Allegato 1 non rientrano nell'elenco A o B di cui all'Allegato II della Direttiva 98/79/CE.**
The devices as per Annex 1 do not do not fall under list A or B of annex II of the Directive 98/79/EC.

> **La presente dichiarazione è stata redatta in conformità all'Allegato III (escluso punto 6) della Direttiva 98/79/CE.**
The present Declaration was drafted in accordance with annex III to Directive 98/79/EC.

Rilasciato */ Released*
Canelli, 26.07.2015

Duilio BUONO
Responsabile Assicurazione Qualità

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ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	*DESCRIPTION*
1011	Contenitori per feci 18ml, PS, con tappo a pressione con paletta	*Faeces containers 18ml, PS, with pressure cap and spoon*
1011/E	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta	*Faeces containers 18ml, PS, with pressure cap and spoon, with label*
1011/E/50	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta, in confezioni da 50 pezzi	*Faeces containers 18ml, PS, with pressure cap and spoon, with label, in bags of 50 pieces*
1011/E/AST	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta	*Faeces containers 18ml, PS, with pressure cap and spoon, with label*
1012	Contenitori per campioni biologici 18ml, PS, con tappo a pressione	*Specimen containers 18ml, PS, with pressure cap*
1013	Contenitori da 18ml, PS, senza tappo	*Containers 18ml, PS, without cap*
1030	Contenitori per urine 130ml, PS, graduati, tappo a pressione	*Graduated urine containers 130ml, PS, pressure cap*
1030/E	Contenitori per urine 130ml, PS, graduati, tappo a pressione, con etichetta	*Graduated urine containers 130ml, PS, pressure cap, with label*
1030/E/CS	Contenitori per urine 130ml, PS, graduati, tappo a pressione, con etichetta, confezione singola	*Graduated urine containers 130ml, PS, pressure cap, with label, individually wrapped*
1030/MO	Contenitori per urine 130ml, PP, graduati, tappo a pressione	*Graduated urine containers 130ml, PP, pressure cap*
1030/MO/E	Contenitori urina 130ml, in PP tappo a pressione, graduati, etichetta	*Graduated urine containers 130ml, PP, pressure cap, label*
1030/MO/T	Contenitori urina 130ml, in PP tappo a pressione inserito, graduati	*Graduated urine containers 130ml, PP, pressure cap*
1030/R	Contenitori per urine 130ml, PS, graduati, tappo a pressione rosso	*Graduated urine containers 130ml, PS, red pressure cap*
1030/S	Contenitori per urine 130ml, PS, graduati, senza tappo	*Graduated urine containers 130ml, PS, without cap*
1030/T	Contenitori per urine 130ml, PS, graduati, tappo a pressione inserito	*Graduated urine containers 130ml, PS, with inserted pressure cap*
1040	Contenitori per urina 120ml, PP, con coperchio autoadesivo	*Graduated urine containers 120ml, PP, with self-adhesive cap*
1040/P	Contenitori per urina 120ml, PS, con coperchio autoadesivo	*Graduated urine containers 120ml, PS, with self-adhesive cap*
1040/P/S	Contenitori per urina 120ml, PS, senza coperchio autoadesivo	*Graduated urine containers 120ml, PS, without self-adhesive cap*
1040/S	Contenitori per urina 120ml, PP, senza coperchio autoadesivo	*Graduated urine containers 120ml, PP, without self-adhesive cap*
1041	Contenitori per campioni biologici 30ml, PS, con tappo a pressione	*Specimen containers 30ml, PS, with pressure cap*
1041/E	Contenitori per campioni biologici 30ml, PS, con tappo a pressione, con etichetta	*Specimen containers 30ml, PS, with pressure cap, with label*
1041/S	Contenitori per campioni biologici 30ml, PS, senza tappo	*Specimen containers 30ml, PS, without cap*
1041/T	Contenitori per campioni biologici 30ml, PS, con tappo a pressione inserito	*Specimen containers 30ml, PS, with inserted pressure cap*
1050	Contenitori per urine 150ml, PS, graduati, tappo a pressione	*Graduated urine containers 150ml, PS, pressure cap*
1050/E	Contenitori per urine 150ml, PS, graduati, tappo a pressione, con etichetta	*Graduated urine containers 150ml, PS, pressure cap, with label*
1050/S	Contenitori per urine 150ml, PS, graduati, senza tappo	*Graduated urine containers 150ml, PS, without cap*
1050/T	Contenitori per urine 150ml, PS, graduati, tappo a pressione inserito	*Graduated urine containers 150ml, PS, with inserted pressure cap*
1051	Contenitori per espettorato 60ml, PS, con tappo a pressione	*Sputum containers 60ml, PS, with pressure cap*
1051/E	Contenitori per espettorato 60ml, PS, con tappo a pressione, con etichetta	*Sputum containers 60ml, PS, with pressure cap, with label*
1051/S	Contenitori per espettorato 60ml, PS, senza tappo a pressione	*Sputum containers 60ml, PS, without pressure cap*
1051/S/CS	Contenitori per espettorato 60ml, PS, senza tappo a pressione, in confezione singola	*Sputum containers 60ml, PS, without pressure cap, individually wrapped*
1051/T	Contenitori per espettorato 60ml, PS, con tappo a pressione inserito	*Sputum containers 60ml, PS, with inserted pressure cap*
1061	Contenitori per campioni biologici 35ml, PS, con tappo a pressione	*Specimen containers 35ml, PS, with pressure cap*
10621	Contenitori rotondi "SECURBOX" da 2.000ml, in PP, con coperchio a pressione in PP e sigillo di sicurezza a strappo. Con supporto di materiale assorbente a 10 fori. Con manico	*Disposable container"SECURBOX"2,000 ml in PP, with lid in PP with security tear seal. It contains inside absorbent material with 10 holes. With handle*
10622	Contenitori rettangolari "SECURBOX" da 5.000ml, in PP, con coperchio a pressione in PP e sigillo di sicurezza a strappo. Con supporto di materiale assorbente a 99 fori. Con manico	*Disposable container"SECURBOX"5,000 ml in PP, with lid in PP with security tear seal. It contains inside absorbent material with 99 holes. With handle*
10631	Contenitori da 5ml, PE, tappo a vite	*Containers 5ml, PE, screw cap*
10632	Contenitori da 30ml, PE, tappo a vite	*Containers 30ml, PE, screw cap*
10633	Contenitori da 90ml, PE, tappo a vite	*Containers 90ml, PE, screw cap*

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COD.	DESCRIZIONE	*DESCRIPTION*
1070	Contenitori modello "Bijou" da 7ml, in PS, Ø20x50mm, con tappo a vite	*Containers "Bijou" type in PS, 7ml, Ø20x50 mm, with screw cap*
1070/E	Contenitori modello "Bijou" da 7ml, in PS, Ø20x50mm, con tappo a vite, con etichetta	*Containers "Bijou" type in PS, 7ml, Ø20x50 mm, with screw cap, with label*
1081	Contenitori per urine 150ml, PS, graduati, tappo a vite	*Graduated urine containers 150ml, PS, screw cap*
1081/CS	Contenitori per urine 150ml, PS, graduati, tappo a vite, in confezione singola	*Graduated urine containers 150ml, PS, screw cap, individually wrapped*
1081/E	Contenitori per urine 150ml, PS, graduati, tappo a vite, con etichetta	*Graduated urine containers 150ml, PS, screw cap, with label*
1081/T	Contenitori urina 150ml, in PS con tappo a vite inserito,	*Graduated urine containers 150ml, PS, screw cap*
1211	Contenitori per feci 60ml, PS, con tappo a pressione con paletta	*Faeces containers 60ml, PS, with pressure cap and spoon*
1211/CS	Contenitori per feci 60ml, PS, con tappo a pressione con paletta	*Faeces containers 60ml, PS, with pressure cap and spoon*
1212	Contenitori per campioni biologici 60ml, PS, con tappo a pressione	*Specimen containers 60ml, PS, with pressure cap*
1212/CS	Contenitori per campioni biologici 60ml, PS, con tappo a pressione, confezione singola	*Specimen containers 60ml, PS, with pressure cap, individually wrapped*
1213	Contenitori da 60ml, PS, senza tappo	*Containers 60ml, PS, without cap*
1230	Contenitori per urine 200ml, PS, graduati, tappo a vite	*Graduated urine containers 200ml, PS, screw cap*
1230/10	Contenitori per urine 200ml, PS, graduati, tappo a vite	*Graduated urine containers 200ml, PS, screw cap*
1230/100	Contenitori per urine 200ml, PS, graduati, tappo a vite	*Graduated urine containers 200ml, PS, screw cap*
1230/CS	Contenitori per urine 200ml, PS, graduati, tappo a vite, confezione singola	*Graduated urine containers 200ml, PS, screw cap, ind. wrapped*
1230/E	Contenitori per urine 200ml, PS, graduati, tappo a vite, con etichetta	*Graduated urine containers 200ml, PS, screw cap, with label*
1230/S/E	Contenitori urina 200ml, in PS senza tappo, graduati,	*Graduated urine containers 200ml, PS, with label*
1230/T	Contenitori urina 200ml, in PS tappo a vite inserito,	*Graduated urine containers 200ml, PS, with inserted screw cap*
1230/TE	Contenitori per urine 200ml, PS, graduati, tappo a vite inserito, con etichetta	*Graduated urine containers 200ml, PS, with inserted screw cap, with label*
12731	Tanica per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	*Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated*
12731/E	Tanica per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata, etichetta	*Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated, with label*
12731/SAC	Taniche in PE da 2.500ml per la raccolta urine 24ore,	*Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated, individually wrapped*
12731K	Tanica per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	*Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated*
14120	Contenitori per istologia da 20ml, in PP, tappo a vite verde	*20 ml Surgical specimen containers in PP, with yellow screw cap*
14120/B	Contenitori per istologia da 20ml, in PP, tappo a vite giallo, etichetta biohazard	*20 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14121	Contenitori per istologia da 40ml, in PP, tappo a vite giallo	*40 ml Surgical specimen containers in PP, with yellow screw cap*
14121/B	Contenitori per istologia da 40ml, in PP, tappo a vite giallo, etichetta biohazard	*40 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14122	Contenitori per istologia da 60ml, in PP, tappo a vite giallo	*60 ml Surgical specimen containers in PP, with yellow screw cap*
14122/B	Contenitori per istologia da 60ml, in PP, tappo a vite giallo, etichetta biohazard	*60 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14123	Contenitori per istologia da 90ml, in PP, tappo a vite giallo	*90 ml Surgical specimen containers in PP, with yellow screw cap*
14123/B	Contenitori per istologia da 90ml, in PP, tappo a vite giallo, etichetta biohazard	*90 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14124	Contenitori per istologia da 120ml, in PP, tappo a vite giallo	*120 ml Surgical specimen containers in PP, with yellow screw cap*
14124/B	Contenitori per istologia da 120ml, in PP, tappo a vite giallo, etichetta biohazard	*120 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14131	Contenitori per biopsie in PS, con tappo a pressione in PE, da 30ml	*Biopsy specimen containers in PS with pressure cap in PE, 30 ml*
14132	Contenitori per biopsie in PS, con tappo a pressione in PE, da 50ml	*Biopsy specimen containers in PS with pressure cap in PE, 50 ml*
14134	Contenitori per biopsie in PS, con tappo a pressione in PE, da 100ml	*Biopsy specimen containers in PS with pressure cap in PE, 100 ml*
14136	Contenitori per biopsie in PS, con tappo a pressione in PE, da 150ml	*Biopsy specimen containers in PS with pressure cap in PE, 150 ml*
14138	Contenitori per biopsie in PS, con tappo a pressione in PE, da 200ml	*Biopsy specimen containers in PS with pressure cap in PE, 200 ml*
14140	Contenitori per biopsie in PS, con tappo a pressione in PE, da 250ml	*Biopsy specimen containers in PS with pressure cap in PE, 250 ml*
14142	Contenitori per pezzi chirurgici 500ml, PE, bocca larga, tappo a pressione	*Surgical specimens containers 500ml, PE, wide opening, with pressure cap*

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COD.	DESCRIZIONE	*DESCRIPTION*
14142/B	Contenitori per pezzi chirurgici 500ml, PE, bocca larga, tappo a pressione, etichetta Biohazard	*Surgical specimens containers 500ml, PE, wide opening, with pressure cap, Biohazard label*
14143	Contenitori per pezzi chirurgici 1.000ml, PE, bocca larga, tappo a pressione	*Surgical specimens containers 1.000ml, PE, wide opening, with pressure cap*
14143/B	Contenitori per pezzi chirurgici 1.000ml, PE, bocca larga, tappo a pressione, etichetta Biohazard	*Surgical specimens containers 1.000ml, PE, wide opening, with pressure cap, Biohazard label*
14144	Contenitori per pezzi chirurgici 1.500ml, PE, bocca larga, tappo a pressione	*Surgical specimens containers 1.500ml, PE, wide opening, with pressure cap*
14144/B	Contenitori per pezzi chirurgici 1.500ml, PE, bocca larga, tappo a pressione, etichetta Biohazard	*Surgical specimens containers 1.500ml, PE, wide opening, with pressure cap, Biohazard label*
14150	Contenitori trasparenti per pezzi chirurgici 150ml, PP, tappo a pressione	*Surgical specimens transparent containers 150ml, PP, with pressure cap*
14150/B	Contenitori trasparenti per pezzi chirurgici 150ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 150ml, PP, with pressure cap, Biohazard label*
14151	Contenitori per istologia da 250ml, in PP, tappo a vite giallo	*250 ml Surgical specimen containers in PP, with yellow screw cap*
14151/B	Contenitori per istologia da 250ml, in PP, tappo a vite giallo, etichetta biohazard	*250 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14152	Contenitori per istologia da 500ml, in PP, tappo a vite giallo	*500 ml Surgical specimen containers in PP, with yellow screw cap*
14152/B	Contenitori per istologia da 500ml, in PP, tappo a vite giallo, etichetta biohazard	*500 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14153	Contenitori per istologia da 1000 ml, in PP, tappo a vite giallo	*1000 ml Surgical specimen containers in PP, with yellow screw cap*
14153/B	Contenitori per istologia da 1000 ml, in PP, tappo a vite giallo, etichetta biohazard	*1000 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label*
14155	Contenitori trasparenti per pezzi chirurgici 250ml, PP, tappo a pressione	*Surgical specimens transparent containers 250ml, PP, with pressure cap*
14155/B	Contenitori trasparenti per pezzi chirurgici 250ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 250ml, PP, with pressure cap, Biohazard label*
14160	Contenitori trasparenti per pezzi chirurgici 500ml, PP, tappo a pressione	*Surgical specimens transparent containers 500ml, PP, with pressure cap*
14160/S	Contenitori trasparenti per pezzi chirurgici 500ml, PP, tappo a pressione, serigrafati	*Surgical specimens transparent containers 500ml, PP, with pressure cap, serigraphed*
14170	Contenitori trasparenti per pezzi chirurgici 1.000ml, PP, tappo a pressione	*Surgical specimens transparent containers 1.000ml, PP, with pressure cap*
14170/S	Contenitori trasparenti per pezzi chirurgici 1.000ml, PP, tappo a pressione, serigrafati	*Surgical specimens transparent containers 1.000ml, PP, with pressure cap, serigraphed*
14175	Contenitori trasparenti per pezzi chirurgici 2.000ml, PP, tappo a pressione	*Surgical specimens transparent containers 2.000ml, PP, with pressure cap*
14175/B	Contenitori trasparenti per pezzi chirurgici 2.000ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 2.000ml, PP, with pressure cap, Biohazard label*
14175/T	Contenitori trasparenti per pezzi chirurgici 2.000ml, PP, tappo a pressione inserito	*Surgical specimens transparent containers 2.000ml, PP, with inserted pressure cap*
14180	Contenitori trasparenti per pezzi chirurgici 3.000ml, PP, tappo a pressione	*Surgical specimens transparent containers 3.000ml, PP, with pressure cap*
14180/B	Contenitori trasparenti per pezzi chirurgici 3.000ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 3.000ml, PP, with pressure cap, Biohazard label*
14180/S	Contenitori trasparenti per pezzi chirurgici 3.000ml, PP, tappo a pressione, serigrafati	*Surgical specimens transparent containers 3.000ml, PP, with pressure cap, serigraphed*
14185	Contenitori trasparenti per pezzi chirurgici 5.000ml, PP, tappo a pressione	*Surgical specimens transparent containers 5.000ml, PP, with pressure cap*
14185/B	Contenitori trasparenti per pezzi chirurgici 5.000ml, PP, tappo a pressione, etichetta Biohazard	*Surgical specimens transparent containers 5.000ml, PP, with pressure cap, Biohazard label*
14190	Contenitori per grossi pezzi chirurgici 5.600ml, PP, tappo a pressione	*Big surgical specimens containers 5.600ml, PP, with pressure cap*
14190/B	Contenitori per grossi pezzi chirurgici 5.600ml, PP, tappo a pressione, etichetta biohazard	*Big surgical specimens containers 5.600ml, PP, with pressure cap, biohazard label*
14192	Contenitori per grossi pezzi chirurgici 2,500ml, PP, tappo a pressione	*Big surgical specimens containers 2,500ml, PP, with pressure cap*
14192/B	Contenitori per grossi pezzi chirurgici 2,500ml, PP, tappo a pressione, etichetta biohazard	*Big surgical specimens containers 2,500ml, PP, with pressure cap, biohazard label*
14195	Contenitori per grossi pezzi chirurgici 11.000ml, PP, tappo a pressione	*Big surgical specimens containers 11.000ml, PP, with pressure cap*
14195/B	Contenitori per grossi pezzi chirurgici 11.000ml, PP, tappo a pressione, etichetta biohazard	*Big surgical specimens containers 11.000ml, PP, with pressure cap, biohazard label*
1560	Contenitori per saliva 30 ml, in PP, tappo a vite,	*Autoclavable sputum collection container 30 ml, in PP, screw cap*
1630	Contenitori da 250 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm	*250 ml specimen containers in PS. With alluminium screw cap with gasket, Ø39 x 60 mm*
1630/E	Contenitori da 250 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm, con etichetta	*250 ml specimen containers in PS. With alluminium screw cap with gasket, Ø39 x 60 mm, with label*
19550	Contenitore per la raccolta delle urine per test antidoping	*Urine containers for testing drugs abuse*

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COD.	DESCRIZIONE	*DESCRIPTION*
2030	Contenitori per campioni biologici 30ml, PP, tappo a vite	*Specimen containers 30ml, PP, with screw cap*
2030/E	Contenitori per campioni biologici 30ml, PP, tappo a vite, etichetta	*Specimen containers 30ml, PP, with screw cap, label*
2030/P	Contenitori per campioni biologici 30ml, PP, tappo a vite rosso non inserito	*Specimen containers 30ml, PP, with red screw cap not inserted*
2030/S	Contenitori per campioni biologici 30ml, PP, con tappo a vite a parte	*Specimen containers 30ml, PP, with screw cap in separate bag*
2030/S/R	Contenitori per campioni biologici 30ml, PP, con tappo a vite a parte rosso	*Specimen containers 30ml, PP, with red screw cap in separate bag*
2040	Contenitori per campioni biologici 60ml, PS, tappo a vite	*Specimen containers 60ml, PS, with screw cap*
2040/B	Contenitori per campioni biologici 60ml, PS, tappo a vite bianco	*Specimen containers 60ml, PS, with white screw cap*
2040/E	Contenitori per campioni biologici 60ml, PS, tappo a vite, con etichetta	*Specimen containers 60ml, PS, with screw cap, with label*
2040/E/R	Contenitori campioni biologici 60ml, PS, tappo inserito rosso	*Specimen containers 60ml, PS, with screw cap, with label*
2040/P	Contenitori campioni biologici 60ml, in PS, Ø35 x 70 mm,	*Specimen containers 60ml, PS, with screw cap*
2040/P/E	Contenitori campioni biologici 60ml, PS, Ø35x70mm, etichetta,	*Specimen containers 60ml, PS, with screw cap, with label*
2040/R	Contenitori per campioni biologici 60ml, PS, tappo a vite rosso	*Specimen containers 60ml, PS, with red screw cap*
2042	Contenitori per campioni biologici 60ml, PS, tappo a vite e paletta	*Specimen containers 60ml, PS, with screw cap and spoon*
2042/E	Contenitori per campioni biologici 60ml, PS, tappo a vite e paletta, con etichetta	*Specimen containers 60ml, PS, with screw cap and spoon, with label*
2050	Contenitori per campioni biologici 60ml, PP, tappo a vite	*Specimen containers 60ml, PP, with screw cap*
2050/100	Contenitori per campioni biologici 60ml, PP, tappo a vite	*Specimen containers 60ml, PP, with screw cap*
2050/B	Contenitori di colore blu per campioni biologici 60ml, PP, tappo a vite	*Specimen containers blue colour 60ml, PP, with screw cap*
2050/C	Tappi a vite colore giallo per contenitori cod. 2050	*Yellow screw cap for containers cod 2050*
2050/CS	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola	*Specimen containers 60ml, PP, with screw cap, ind. wrapped*
2050/DDK	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito rosso	*Specimen containers 60ml, PP, with red inserted screw cap*
2050/E	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito, con etichetta	*Specimen containers 60ml, PP, with inserted screw cap, with label*
2050/E/S	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito, con etichetta	*Specimen containers 60ml, PP, with screw cap not inserted, with label*
2050/P	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito	*Specimen containers 60ml, PP, with screw cap not inserted*
2050/P/E	Contenitori campioni biologici 60ml, PP, Ø35x70mm, graduati,	*Specimen containers 60ml, PP, with screw cap not inserted*
2050/PR	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito colore rosso	*Specimen containers 60ml, PP, with screw cap not inserted red colour*
2050/R	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito colore rosso	*Specimen containers 60ml, PP, with screw cap inserted red colour*
2050/S	Contenitori per campioni biologici 60ml, PP, senza tappo	*Specimen containers 60ml, PP, without cap*
2050/T	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito	*Specimen containers 60ml, PP, with inserted screw cap*
2050/TAPPO/B	Tappi a vite colore blu per contenitori cod. 2050	*Blue screw cap for containers cod 2050*
2050P	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito	*Specimen containers 60ml, PP, with screw cap not inserted*
2052	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2052/10	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2052/100	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2052/CS	Contenitori per feci 60ml, PP, con tappo a vite con paletta, confezione singola	*Faeces containers 60ml, PP, with screw cap and spoon, individually wrapped*
2052/E	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta	*Faeces containers 60ml, PP, with screw cap and spoon, with label*
2052/E/CS	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta, confezione singola	*Faeces containers 60ml, PP, with screw cap and spoon, with label, individually wrapped*
2052/R	Contenitori per feci 60ml, PP, con tappo a vite rosso con paletta	*Faeces containers 60ml, PP, with red screw cap and spoon*
2052/T5	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2062	Contenitori per feci da 60 ml, in PP, tappo a vite	*Faeces containers in PP 60ml, screw cap*
2062/10	Contenitori per feci da 60 ml, in PP, tappo a vite	*Faeces containers in PP 60ml, screw cap*
2062/E	Contenitori per feci da 60ml, in PP, tappo vite con paletta, etichetta	*Faeces containers in PP 60ml, screw cap, with label*
2062/P	Contenitori per feci da 60 ml, in PP, tappo a vite a parte	*Faeces containers in PP 60ml, not assembled screw cap*

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COD.	DESCRIZIONE	*DESCRIPTION*
2072	Contenitori per feci da 60 ml, in PS, tappo a vite	*Faeces containers in PS 60ml, screw cap*
2072/E	Contenitori per feci da 60ml, in PS, tappo vite con paletta, etichetta	*Faeces containers in PS 60ml, screw cap, with label*
2072/P	Contenitori per feci da 60 ml, in PS, tappo a vite a parte	*Faeces containers in PS 60ml, not assembled screw cap*
2120	Contenitori per urine 150ml, PP, graduati, tappo a vite	*Graduated urine containers 150ml, PP, screw cap*
2120/100	Contenitori per urine 150ml, PP, graduati, tappo a vite	*Graduated urine containers 150ml, PP, screw cap*
2120/50	Contenitori per urine 150ml, PP, graduati, tappo a vite	*Graduated urine containers 150ml, PP, screw cap*
2120/B	Contenitori per urine 150ml, PP, graduati, tappo a vite bianco	*Graduated urine containers 150ml, PP, white screw cap*
2120/CS	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici	*Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic*
2120/CS/M	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici	*Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic*
2120/CS/MI	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici	*Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic*
2120/E	Contenitori per urine 150ml, PP, graduati, tappo a vite, con etichetta	*Graduated urine containers 150ml, PP, screw cap, with label*
2120/E/CS	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici, con etichetta	*Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic, with label*
2120/ES	Contenitori per urine 150ml, PP, graduati, tappo a vite, con etichetta non applicata	*Graduated urine containers 150ml, PP, screw cap, with label in separate bag*
2120/N	Contenitori per urine 150ml, PP, graduati, tappo a vite neutro	*Graduated urine containers 150ml, PP, neutral screw cap*
2120/R	Contenitori per urine 150ml, PP, graduati, tappo a vite rosso	*Graduated urine containers 150ml, PP, red screw cap*
2120/S	Contenitori per urine 150ml, PP, graduati, senza tappo	*Graduated urine containers 150ml, PP, without cap*
2120/T	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito	*Graduated urine containers 150ml, PP, with inserted screw cap*
2120/T/100	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito, confezioni da 100 pcs	*Graduated urine containers 150ml, PP, with inserted screw cap, bags of 100 pcs*
2120/T/N	Contenitore urina 150ml, in PP tappo a vite neutro inserito,	*Graduated urine containers 150ml, PP, with inserted screw cap*
2120/T5	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito, confezioni da 5 pcs	*Graduated urine containers 150ml, PP, with inserted screw cap, bags of 5 pcs*
2120/T50	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito, confezioni da 50 pcs	*Graduated urine containers 150ml, PP, with inserted screw cap, bags of 50 pcs*
2120/TB	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito bianco	*Graduated urine containers 150ml, PP, with inserted white screw cap*
2120/TB	Contenitori urina 150ml, in PP con tappo a vite bianco	*Graduated urine containers 150ml, PP, with inserted screw cap*
2120/TE	Contenitori urina 150ml, in PP tappo vite azzurro inserito,	*Graduated urine containers 150ml, PP, with inserted screw cap*
2120/TN	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito di colore neutro	*Graduated urine containers 150ml, PP, with inserted screw cap neutral colour*
2120/TR	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito colore rosso	*Graduated urine containers 150ml, PP, with red inserted screw cap*
2120/V/500	Contenitori per urine 150ml, PP, graduati, tappo a vite verde	*Graduated urine containers 150ml, PP, screw cap green colour*
2220	Contenitori per urine 200ml, PP, graduati, tappo a vite	*Graduated urine containers 200ml, PP, screw cap*
2220/250	Contenitori urina 200ml, in PP tappo a vite, graduati,	*Graduated urine containers 200ml, PP, screw cap*
2220/CS	Contenitori per urine 200ml, PP, graduati, tappo a vite, confezione singola	*Graduated urine containers 200ml, PP, screw cap, ind. wrapped*
2220/E	Contenitori per urine 200ml, PP, graduati, tappo a vite, con etichetta	*Graduated urine containers 200ml, PP, screw cap, with label*
2220/E/CS	Contenitori per urine 200ml, PP, graduati, tappo a vite, con etichetta, confezione singola	*Graduated urine containers 200ml, PP, screw cap, with label, individually wrapped*
2220/R	Contenitori per urine 200ml, PP, graduati, tappo a vite rosso	*Graduated urine containers 200ml, PP, red screw cap*
2220/S	Contenitori per urine 200ml, PP, graduati, senza tappo a vite	*Graduated urine containers 200ml, PP, without screw cap*
2220/T	Contenitori per urine 200ml, PP, graduati, tappo a vite inserito	*Graduated urine containers 200ml, PP, with inserted screw cap*
2250	Contenitori campioni biologici da 40 ml, in PP	*Specimen containers 40 ml, in PP*
2420	Contenitori per urine 150ml, PP, graduati, tappo a vite e tappino per prelievo campioni	*Graduated urine containers 150ml, PP, screw cap and plug*
2420/R	Contenitori per urine 150ml, PP, graduati, tappo a vite rosso e tappino per prelievo campioni	*Graduated urine containers 150ml, PP, with screw cap and plug red colour*
2420/TR	Contenitori urine 150ml, PP, graduati, tappo a vite rosso e tappino prelievo campioni inserito	*Graduated urine containers 150ml, PP, with inserted screw cap and plug red colour*
2440	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm.	*Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm*

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COD.	DESCRIZIONE	*DESCRIPTION*
2440/CS	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm, conf. singola	*Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm, individually wrapped*
2440/E	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm, con etichetta	*Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm, with label*
2440/E/CS	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm, con etichetta, conf. singola	*Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm, with label, individually wrapped*
2440/P	Contenitori campioni biologici 60ml, PS, con tappo a parte,	*Specimen containers in PS with screw cap, 60 ml, Ø 38 x 65 mm*
2442	Contenitori per feci in PS con tappo a vite e con paletta, 60 ml, Ø 38 x 65 mm	*Faeces containers in PS with screw cap and spoon, 60 ml, Ø 38 x 65 mm*
2442/E	Contenitori per feci in PS con tappo a vite e con paletta, 60 ml, Ø 38 x 65 mm, con etichetta.	*Faeces containers in PS with screw cap and spoon, 60 ml, Ø 38 x 65 mm, with label*
2442/R	Contenitori per feci in PS con tappo a vite rosso e con paletta, 60 ml, Ø 38 x 65 mm	*Faeces containers in PS with red screw cap and spoon, 60 ml, Ø 38 x 65 mm*
2450	Contenitori per campioni biologici 60ml, PP, tappo a vite	*Specimen containers 60ml, PP, with screw cap*
2450/B	Contenitori per campioni biologici 60ml, PP, tappo a vite bianco	*Specimen containers 60ml, PP, with white screw cap*
2450/CS	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola	*Specimen containers 60ml, PP, with screw cap, ind. wrapped*
2450/E	Contenitori per campioni biologici 60ml, PP, tappo a vite, con etichetta	*Specimen containers 60ml, PP, with screw cap, with label*
2450/P	Contenitori campioni biologici 60ml, in PP, Ø38 x 65 mm,	*Specimen containers 60ml, PP, with screw cap, with label*
2450/R	Contenitori per campioni biologici 60ml, PP, tappo a vite colore rosso	*Specimen containers 60ml, PP, with red screw cap*
2452	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2452/E	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta	*Faeces containers 60ml, PP, with screw cap and spoon, with label*
2452/E/CS	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta, confezione singola	*Faeces containers 60ml, PP, with screw cap and spoon, with label, individually wrapped*
2452/R	Contenitori per feci 60ml, PP, con tappo a vite rosso e con paletta	*Faeces containers 60ml, PP, with red screw cap and with spoon*
2452/T/5	Contenitori per feci 60ml, PP, con tappo a vite con paletta	*Faeces containers 60ml, PP, with screw cap and spoon*
2580	Contenitori per campioni biologici 25ml, PS, tappo a vite	*Specimen containers 25ml, PS, with screw cap*
2580/B	Contenitori per campioni biologici 25ml, PS, tappo a vite bianco	*Specimen containers 25ml, PS, with white screw cap*
2580/E	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta	*Specimen containers 25ml, PS, with screw cap, with label*
2580/E/CS	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta, confezione singola	*Specimen containers 25ml, PS, with screw cap, with label, individually wrapped*
2580/E/P	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito, con etichetta	*Specimen containers 25ml, PS, with screw cap not inserted, with label*
2580/E/P/W	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito, con etichetta	*Specimen containers 25ml, PS, with screw cap not inserted, with label*
2580/E/W	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta	*Specimen containers 25ml, PS, with screw cap, with label*
2580/EB	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta bianca	*Specimen containers 25ml, PS, with screw cap, with white label*
2580/ER	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito, con etichetta	*Specimen containers 25ml, PS, with not inserted screw cap, with label*
2580/P	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito	*Specimen containers 25ml, PS, with not inserted screw cap*
2580/PB	Contenitori campioni biologici 25ml, in PS, Ø25 x 90 mm,	*Specimen containers 25ml, PS, with not inserted screw cap*
2580/S	Contenitori per campioni biologici 25ml, PS, senza tappo	*Specimen containers 25ml, PS, without cap*
2580/TAPPO/A	Tappo a vite colore azzurro per contenitori cod. 2580/2680	*Light blue screw cap for containers cod. 2580/2680*
2580/TBIANCO	Tappo a vite colore bianco per contenitori cod. 2580/2680	*White screw cap for containers cod. 2580/2680*
2580/W	Contenitori per campioni biologici 25ml, PS, tappo a vite bianco non inserito	*Specimen containers 25ml, PS, with white not inserted screw cap*
2580P	Contenitori campioni biologici 25ml, PS, con tappo a vite	*Specimen containers 25ml, PS, with white not inserted screw cap*
2588	Contenitori per feci 25ml, PS, con tappo a vite con paletta	*Faeces containers 25ml, PS, with screw cap and spoon*
2588/E	Contenitori per feci 25ml, PS, con tappo a vite con paletta, con etichetta	*Faeces containers 25ml, PS, with screw cap and spoon, with label*
2588/E/CS	Contenitori per feci 25ml, PS, con tappo a vite con paletta, con etichetta, confezione singola	*Faeces containers 25ml, PS, with screw cap and spoon, with label, individually wrapped*
2588/EB	Contenitori per feci 25ml, PS, con tappo a vite con paletta, con etichetta bianca	*Faeces containers 25ml, PS, with screw cap and spoon, with white label*
2588/P	Contenitori per feci 25ml, PS, con tappo a vite con paletta a parte	*Faeces containers 25ml, PS, with screw cap and spoon in separate bag*
2588P	Paletta in polipropilene bianco	*Spoon in white polypropylene*

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COD.	DESCRIZIONE	*DESCRIPTION*
2640	Contenitori da 60 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm	*60 ml specimen containers in PS. With alluminium screw cap with gasket, Ø39 x 60 mm*
2640/E	Contenitori da 60 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm, con etichetta	*60 ml specimen containers in PS. With alluminium screw cap with gasket, Ø39 x 60 mm, with label*
2680	Contenitori per campioni biologici 25ml, PP, tappo a vite	*Specimen containers 25ml, PP, with screw cap*
2680/E	Contenitori per campioni biologici 25ml, PP, tappo a vite inserito, con etichetta	*Specimen containers 25ml, PP, with inserted screw cap, with label*
2680/P	Contenitori per campioni biologici 25ml, PP, tappo a vite non inserito	*Specimen containers 25ml, PP, with not inserted screw cap*
2680/S	Contenitori per campioni biologici 25ml, PP, senza tappo a vite	*Specimen containers 25ml, PP, without screw cap*
2688	Contenitori per feci 25ml, PP, con tappo a vite con paletta	*Faeces containers 25ml, PP, with screw cap and spoon*
2688/E	Contenitori per feci 25ml, PP, con tappo a vite con paletta, con etichetta	*Faeces containers 25ml, PP, with screw cap and spoon, with label*
2688/E/CS	Contenitori per feci 25ml, PP, con tappo a vite con paletta, con etichetta, in confezione singola	*Faeces containers 25ml, PP, with screw cap and spoon, with label, individually wrapped*
5024	Bottiglie per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	*Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap, graduated*
5024/E	Bottiglie per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata, etichetta	*Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap, graduated, with label*
5024/F	"24 ore" da 2.500 ml tipo bottiglia in pe	*Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap*
5024K	Bottiglie per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	*Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap, graduated*
5050/S	Contenitori per feci da 60ml, in PP, senza tappo	*Faeces containers in PP 60ml, without cap*
5120	Contenitore per urine in PP da 120ml, tappo con sistema di prelievo sottovuoto.	*120 ml urine containers in PP, with screw cap with device for vacuum tube*
5120/CS	Contenitore per urine in PP da 120ml, tappo con sistema di prelievo sottovuoto, confezione singola	*120 ml urine containers in PP, with screw cap with device for vacuum tube, individually wrapped*
5434	Contenitori per la raccolta delle urine nelle 24 ore, 2.000ml, PE, tappo a vite, graduata	*Square containers for 24 hours urine collection, 2.500ml, PE, graduated, screw cap*
5434/M	Contenitori per la raccolta delle urine nelle 24 ore, 2000ml, PE, tappo vite, graduata, marrone	*Square containers for 24 hours urine collection, 2.500ml, PE, graduated, screw cap, brown*
5471	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, con tappo per il prelievo con provetta tipo sottovuoto	*2000 ml Square graduated containers for 24 hours urine collection with ergonomic handle. Screw cap complete of sampling device for vacuum test tubes.*
5472	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto	*2000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes.*
5671	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, con tappo per il prelievo con provetta tipo sottovuoto e sonda prelievo	*2000ml Square graduated containers for 24 hours urine collection with ergonomic handle. Screw cap complete of sampling device for vacuum test tubes and sampling probe*
5672	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto e sonda prelievo	*2000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes and sampling probe*
5731	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 3000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto	*3.000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes*
5732	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 3000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto e sonda prelievo	*3.000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes and sampling probe*
6840	Contenitore per trasporto campioni con coperchio ermetico	*Test tubes securbox with hermetic lid*

Duilio BUONO
Responsabile Assicurazione Qualità

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
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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

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