Digitally signed by Ceaicovschi Tudor
Date: 2024.12.24 09:05:41 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number: **MD 69326**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-10-25
Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14
Expiry Date: 2027-04-13

...making excellence a habit.™

Certificate No: **MD 69326**

Location	Registered Activities
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Sunderland Enterprise Park Colima Avenue Sunderland SR5 3XB United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Queensway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 0SD United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

Original Registration Date: 2002-10-25

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

Declaration of Conformity

HL-7- 0135 DC DOI 2013/10 (6)

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

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

Product Code	Description	GMDN Classification Code
5183	Routine Control SA	30590

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

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

Signed: Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0137 DC DOI 2013/10 (6)

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

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

Product Code	Description	GMDN Classification Code
5186	Routine Control N	30590

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

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

Signed: Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0138 DC DOI 2013/10 (6)

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

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

Product Code	Description	GMDN Classification Code
5187	Routine Control A	30590

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

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

Signed: Date: 31st October 2013

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

Declaration of Conformity

HL-7- 0640DC DOI 2015/07 (1)

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

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

Product Code	Description	GMDN Classification Code
5504R	Calibration Plasma	55995

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

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

Signed: Date: 30 Jul 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
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www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7-0664DC DOI 2015/08 (1)

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

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

Product Code	Description	GMDN Classification Code
5267L	Thromboplastin L	55983

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

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

Signed: Date: 06 Aug 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0512 DC DOI 2013/08 (4)

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

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

Product Code	Description	GMDN Classification Code
5556	Clauss Fibrinogen 50	55997
5556H	Clauss Fibrinogen 50	55997

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

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 05 Aug 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

CERTIFICAT

CERTIFICATE OF REGISTRATION

N° 10462 rev. 8

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ELITECH CLINICAL SYSTEMS SAS

Zone Industrielle

61500 SEES FRANCE

pour les activités

for the activities

Conception, production, contrôle et commercialisation de produits de chimie cliniques pour le diagnostic in vitro. Validation de la combinaison réactifs et automates. Distribution d'automates et de produits de chimie cliniques pour le diagnostic in vitro.

Design, production, control and sales of clinical chemistry products intended to be used for in vitro diagnostics. Validation of the combination reagents and analyzers. Distribution of clinical chemistry analyzers and products for in vitro diagnostics.

réalisées sur le(s) site(s) de

performed on the location(s) of

ELITech Clinical Systems SAS
Zone industrielle - 61500 SEES - FRA

est conforme aux exigences des normes internationales

complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité */ Effective date :* **July 25th, 2023 (included)**

Valable jusqu'au */ Expiry date :* **July 27th, 2026 (included)**

Etabli le */ Issued on :* **July 25th, 2023**

GMED SAS GMED SAS

DocuSigned by:
Marjorie PERRIMON
F6FB7BBEC7B144D...

On behalf of the President,
Marjorie PERRIMON
Certification Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ-F-V0-07-2018

GMED N° 10462–8

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 10462-7

ELITechGroup B.V.
P.O.Box 100
6950 AC Dieren
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands
T: +31 313 430 500
F: +31 313 427 807
info.ecsnl@elitechgroup.com
www.elitechgroup.com
Chamber of Commerce 09175642

To: Whom it May Concern

Regulatory status of parts & accessories

As mentioned on the current Declarations of Conformity of our Clinical Chemistry Analyzers also the accessories conform to the provisions of the EU Directive on In Vitro Diagnostic Medical Devices (98/79/EC). This applies to the parts and accessories as mentioned in the attached list.

'IVD accessory' means an article which, whilst not being an IVD medical device, is intended specifically by its manufacturer to be used together with an IVD device to enable that IVD device to be used in accordance with its intended purpose.

ELITechGroup B.V.

Adriaan P. Intveld
Manager Quality Assurance & Regulatory Affairs

ELITechGroup
CLINICAL SYSTEMS

Part number	Description	IVD medical device	IVD accessory	general laboratory use	spare part	supporting part
1540-001	Anti-Slip sheet					✓
2206-007	Cooling Liquid (1 L)					✓
3062-021	Sample cup (1000 pcs)		✓			
3062-033	Sample tube 6 ml (500 pcs)					✓
3062-040	Water container 10 L					✓
3062-041	Water container 5 L					✓
3066-155	Syringe 100 µl		✓			
3066-156	Syringe 1 ml		✓			
3069-040	Keyboard Dust cover					✓
3069-047	Keyboard Dust cover					✓
3070-518	Cap holder					✓
3070-538	Cap rotor Left					✓
3070-539	Cap rotor right					✓
3201-002	Dichromate 8 Abs (25ml)		✓			
3365-192	USB Stick					✓
3374-003	Mains cable (USA)					✓
3374-059	Pumpunit cable		✓			
3374-066	Mains cable					✓
3374-097	Serial Null-modem cable					✓
3374-286	USB Extension cable					✓
4804-038	Reagent identification Disc					✓
6001-826	Diluted Waste container		✓			
6001-827	Concentrated Waste container		✓			
6001-860	Water container		✓			
6001-861	Tube assy (analyser)		✓			
6001-872	Tube assy (cooling unit)		✓			
6002-102	Assorter unit				✓	
6002-386	System software on CD		✓			
6002-706	Reaction Rotor set (3 pcs)		✓			
6002-726	System Disc		✓			
6002-817	Bottle 30 ml (20 pcs)		✓			
6002-818	Bottle 15 ml (20 pcs)		✓			
6002-904	Water container 5 L		✓			
6002-910	Assorter unit				✓	
6002-913	External tubing		✓			
6003-074	System software on USB stick		✓			
6003-444	Diluted Waste Container 5 L		✓			
6003-466	Keyboard Support option					✓
6003-797	CW Waste Container 2 L		✓			
6003-808	Assorter unit				✓	

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

ELITechGroup
EMPOWERING IVD

DECLARATION DE CONFORMITE CE

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

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

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

DECLARATION OF EC CONFORMITY

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

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

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

DECLARACIÓN CE DE CONFORMIDAD

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

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

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

Sées, le 12 Mai 2021

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

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

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

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

Vla

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

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Abbott Laboratories
Diagnostics Division
100 Abbott Park Road
Abbott Park
Illinois
60064
USA

Holds Certificate Number: FM 743464

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, Manufacture, Development, Management of Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 2018-10-12
Effective Date: 2024-10-13
Latest Revision Date: 2024-09-19
Expiry Date: 2027-10-12

...making excellence a habit.™

Certificate No: FM 743464

Location	Registered Activities
Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park Illinois 60064 USA	Design, Manufacture, Development, Management of Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Abbott Laboratories Diagnostics Division - Conway Park 675 North Field Drive Lake Forest Illinois 60045 USA	Oversight of the Quality Management System for the Abbott Diagnostics Division Sites
Abbott Laboratories Diagnostics Division - K Complex - Distribution Center Route 41 & Martin Luther King Drive North Chicago Illinois 60064 USA	QC Inspection of incoming materials and distribution of IVD products including test kits, reagents, accessories and instruments.

Original Registration Date: 2018-10-12

Effective Date: 2024-10-13

Latest Revision Date: 2024-09-19

Expiry Date: 2027-10-12

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Abbott Laboratories
Diagnostics Division
100 Abbott Park Road
Abbott Park
Illinois
60064
USA

Holds Certificate Number: MD 743461

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, Manufacture and Distribution of In Vitro Diagnostic Medical Devices used in the Diagnosis, Management and Detection of Cancer, Autoimmune Status, Cardiac Markers, Endocrine Disorders, and for Therapeutic Drug Monitoring.

Design, Development, Manufacture, Installation, Service and Distribution of In Vitro Diagnostic Medical Devices for Immunoassay and Clinical Chemistry Systems.

Design, Development, Manufacture, Installation, Service and Distribution of In Vitro Diagnostic medical devices including Analyzers, Reagents, and related Accessories for the identification of hematologic parameters.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-06-01
Latest Revision Date: 2024-10-03

Effective Date: 2024-10-13
Expiry Date: 2027-10-12

...making excellence a habit.™

Certificate No: MD 743461

Location	Registered Activities
Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park Illinois 60064 USA	Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Abbott Laboratories Diagnostics Division - Conway Park 675 North Field Drive Lake Forest Illinois 60045 USA	Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
Abbott Laboratories Diagnostics Division - K Complex - Distribution Center Route 41 & Martin Luther King Drive North Chicago Illinois 60064 USA	QC inspection of incoming materials and distribution of IVD products including test kits, reagents, accessories and instruments.

Original Registration Date: 2021-06-01

Effective Date: 2024-10-13

Latest Revision Date: 2024-10-03

Expiry Date: 2027-10-12

Abbott

Declaration of Conformity

Certificate Identification: SC-09H60

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

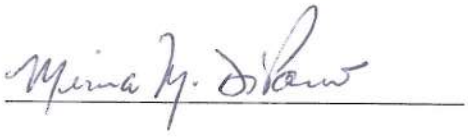
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H60-01	58236	CELL-DYN Emerald 22 Easy Cleaner	**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 Avantor Performance Materials B.V. Teugseweg 20 Deventer, Overijssel Netherlands 7418 AM Avantor Performance Materials Poland S.A. ul. Sowinskiego 11 44-101 Gliwice, Poland
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:	Kevin Richardson	Full Name:	Mirna DiPano
Position:	Manager, Supplier Quality	Position:	Director of Regulatory Affairs
Date of Approval:	10-July-2017	Date of Approval:	10-July-2017
Date Issued:	JUL 10 2017	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V1, April 15, 2016	Effective (Date or Lot Number):	JUL 10 2017

Abbott

Declaration of Conformity

Certificate Identification: SC-09H61

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
09H61-01	61165	CELL-DYN Emerald 22 LYSE	**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 BIT Group France Parc Euromedecine II, Rue de la Valsiere 34 099 – Montpellier, Cedex 5 France
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:	Kevin Richardson	Signature:	Mirna M. DiPano
Full Name:	Kevin Richardson	Full Name:	Mirna DiPano
Position:	Manager, Supplier Quality	Position:	Director of Regulatory Affairs
Date of Approval:	10-July-2017	Date of Approval:	10-July-2017
Date Issued:	JUL 10 2017	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V1, April 15, 2016	Effective (Date or Lot Number):	JUL 10 2017

Abbott

Declaration of Conformity

Certificate Identification: SC-09H62

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
09H62-01	58237	CELL-DYN Emerald 22 DILUENT	**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 Avantor Performance Materials B.V. Teugseweg 20 Deventer, Overijssel Netherlands 7418 AM Avantor Performance Materials Poland S.A. ul. Sowinskiego 11 44-101 Gliwice, Poland
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:	Kevin Richardson	Signature:	Mirna M. DiPano
Full Name:	Kevin Richardson	Full Name:	Mirna DiPano
Position:	Manager, Supplier Quality	Position:	Director of Regulatory Affairs
Date of Approval:	10-July-2017	Date of Approval:	10-July-2017
Date Issued:	JUL 10 2017	Place Issued:	Abbott Santa Clara
Supersedes:	IRI S V1, April 15, 2016	Effective (Date or Lot Number):	JUL 10 2017

Abbott

Declaration of Conformity

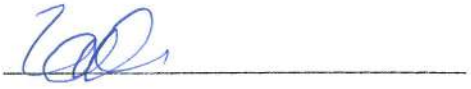
Certificate Identification:	SC-09H72
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address:	Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H72-01	55866	CELL-DYN 22 Plus Control, Full Pack	**Self-declared**
09H72-02	55866	CELL-DYN 22 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 Streck 7002 S. 109th Street La Vista, NE 68128 USA
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:		Signature:	
Full Name:	Kevin Richardson	Full Name:	Zaman Khan
Position:	Manager, Supplier Quality	Position:	Associate Director, Regulatory Affairs
Date of Approval:	11-APR-2016	Date of Approval:	11-Apr-2016
Date Issued:	APR 15 2016	Place Issued:	Abbott Santa Clara
Supersedes:	N/A	Effective (Date or Lot Number):	APR 15 2016

Abbott

Declaration of Conformity

Certificate Identification:	SC-09H73
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
09H73-01	55865	CELL-DYN 22 Plus Calibrator	**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 Streck 7002 S. 109th Street La Vista, NE 68128 USA
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:		Signature:	
Full Name:	Kevin Richardson	Full Name:	Zaman Khan
Position:	Manager, Supplier Quality	Position:	Associate Director, Regulatory Affairs
Date of Approval:	11-APRIL-2016	Date of Approval:	11-Apr-2016
Date Issued:	APR 15 2016	Place Issued:	Abbott Santa Clara
Supersedes:	N/A	Effective (Date or Lot Number):	APR 15 2016

CERTIFICATO N° 505SGQ06

CERTIFICATE N° 505SGQ06

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

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

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

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

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile. Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro. Commercializzazione di articoli da laboratorio.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices. Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics. Marketing of laboratory items.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2023-10-24	2026-10-29

Settore IAF 14 - 29

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

CERTIFICATO N° 505DM09

CERTIFICATE N° 505DM09

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

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

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2021 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile.
Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field.
Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices.
Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
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In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

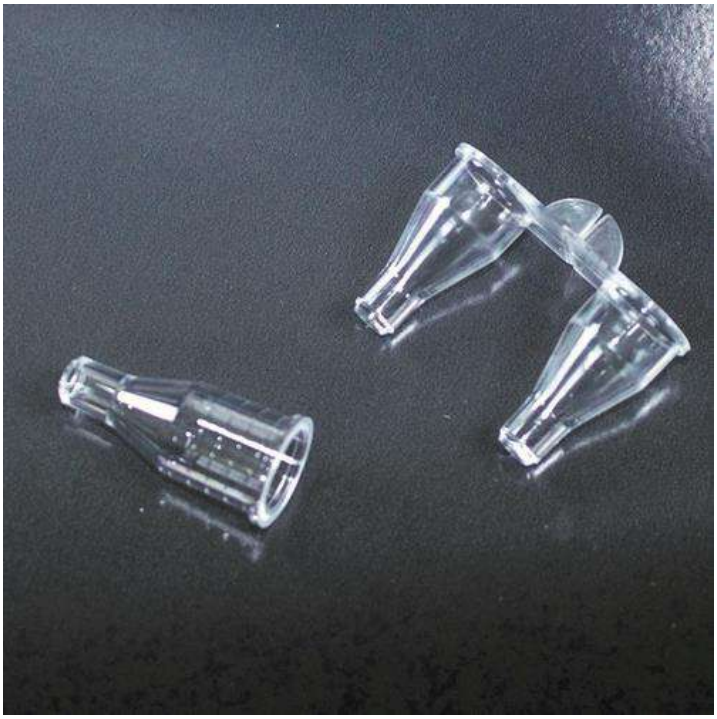
Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2023-10-24	2026-10-29

SSQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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

DATA SHEET



CUVETTES FOR COAGULOMETER TECO®, DIAMED®, DIALAB®

In polystyrene with high optical transparency.

Cod.	Type	Vol. ml	Dim. mm
5951	1 cell	0.8	Ø 10 x 23.4
5961	2 cells	0.6	Ø 10 x 23.4 x 29.7

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV SÜD Product Service

Certificate

No. Q5 020747 0242 Rev. 02

Holder of Certificate: **Nova Biomedical Corporation**
200 Prospect Street
Waltham MA 02454
USA

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Reagents (Calibrators, Controls, Reagents, Sensors and Test Cartridges) and Instruments for Clinical Chemistry, Blood Gas and Hematology, including Near Patient / Point of Care and Self-Testing devices; The provision of manufacturing services of In-Vitro Diagnostic Reagents (Calibrators, Controls) for Clinical Chemistry, Blood Gas and Hematology, In-Vitro Diagnostic General Use Consumables; and Distribution of Lancets.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 020747 0242 Rev. 02

Report No.: 72198686

Valid from: 2024-10-25
Valid until: 2027-10-24

Date, 2024-10-04

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

TÜV SÜD Product Service

Certificate

No. Q5 020747 0242 Rev. 02

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Nova Biomedical Corporation
200 Prospect Street, Waltham MA 02454, USA

Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Reagents (Calibrators, Controls, Reagents, Sensors and Test Cartridges) and Instruments for Clinical Chemistry, Blood Gas and Hematology, including Near Patient / Point of Care and Self-Testing devices; the provision of manufacturing services of In-Vitro Diagnostic Reagents (Calibrators, Controls) for Clinical Chemistry, Blood Gas and Hematology and In-Vitro Diagnostic General Use Consumables.

Nova Biomedical Corporation
39 Manning Road, Billerica MA 01821, USA

Production of Self-Testing and Near Patient / Point of Care test strips.

Nova Biomedical Corporation
165 Lexington Road, Billerica MA 01821, USA

Production of Self-Testing and Near Patient / Point of Care Instruments
.

Nova Biomedical Corporation
4 Enterprise Road, Billerica MA 01821, USA

Production of In-Vitro Diagnostic Instruments including Near Patient / Point of Care; Distribution of Finished Goods; Distribution of Lancets.

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

TÜV®

nova biomedical

Self-Declaration of Conformity To European Parliament and Council Directive 98/79/EC In Vitro Diagnostic Medical Device Directive (IVDD)

Product name:	Nova Stat Profile Prime Plus Analyzer System including Reagents, Calibrators and Controls
Catalog Numbers:	List Attached (Two Pages)
Classification:	Other/General
Manufacturer:	Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454 USA
Representative:	William Jacques, Director of Regulatory and Quality
Authorized Representative:	Nova Biomedical GmbH Hessenring 13 A, Geb. G 64546 Mörfelden-Walldorf Germany Tel: +49 6105 4505-0
Conformity Assessment Route:	Annex III

Nova Biomedical, Inc. declares that the products listed are in conformity with the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices, including applicable essential requirements of Annex I for legal application of the CE Mark. All supporting documentation is retained under the premises of the manufacturer.

Nova Biomedical, Inc. declares that the electronic products listed are in conformity with the provisions of the Council Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Standards Applied:

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 50581:2012	Technical Documentation for the Assessment of Electrical and Electronic Products with Respect to the Restriction of Hazardous Substances
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-2:101:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Signature: _____

William Jacques, Director of Regulatory and Quality

CE

Date: Jul/24/2020

List of Catalog Items Covered:

Catalog Number	Product Name	Global Medical Device Nomenclature (GMDN) Name	GMDN Number	DIMDI EDMS Code
57400	Stat Profile Prime Plus® Analyzer	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
59508	Stat Profile Prime Plus® Analyzer (Remanufactured)	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57820	Stat Profile Prime Plus MicroSensor Card™ with COOX	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57821	Stat Profile Prime Plus MicroSensor Card™ BUN, Creatinine	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57822	Stat Profile Prime Plus MicroSensor Card™ with COOX (High Volume)	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57823	Stat Profile Prime Plus Reference Cartridge	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57825	Stat Profile Prime Plus Calibrator Cartridge 100 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57826	Stat Profile Prime Plus Calibrator Cartridge 200 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57827	Stat Profile Prime Plus Calibrator Cartridge 300 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57828	Stat Profile Prime Plus Calibrator Cartridge 400 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57829	Stat Profile Prime Plus Calibrator Cartridge 500 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57831	Stat Profile Prime Plus Calibrator Cartridge 100 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57832	Stat Profile Prime Plus Calibrator Cartridge 200 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57833	Stat Profile Prime Plus Calibrator Cartridge 300 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57834	Stat Profile Prime Plus Calibrator Cartridge 400 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57835	Stat Profile Prime Plus Calibrator Cartridge 500 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57838	Stat Profile Prime Plus Auto QC Cartridge 160 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57839	Stat Profile Prime Plus Auto QC Cartridge 320 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57840	Stat Profile Prime Plus Auto QC Cartridge 480 Sample	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57841	Stat Profile Prime Plus Auto QC Cartridge 105 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57842	Stat Profile Prime Plus Auto QC Cartridge 210 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57843	Stat Profile Prime Plus Auto QC Cartridge 315 Sample with Creat / BUN	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57844	Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1, 2, 3	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57845	Stat Profile Prime Plus Ampuled Controls Chemistry Levels 4,5	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
58379	Stat Profile Prime Plus BUN, Creatinine - Blank Sensor Card	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
58642	Stat Profile Prime Plus MicroSensor Card™	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
58643	Stat Profile Prime Plus MicroSensor Card™ (High Volume)	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02

Catalog Number	Product Name	Global Medical Device Nomenclature (GMDN) Name	GMDN Number	DIMDI EDMS Code
55229	Nova Linearity Level 1,2,3,4	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
56198	Linearity Standard Set G Multipack	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-90-00
61656	Nova Linearity Creatinine/BUN/Hct Levels 1,2,3,4	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-90-00

nova biomedical

Self-Declaration of Conformity To European Parliament and Council Directive 98/79/EC
In Vitro Diagnostic Medical Device Directive (IVDD)

Product name:	Nova Stat Profile Prime Analyzer System Family including Reagents, Calibrators and Controls
Catalog Numbers:	List Attached (two pages)
Classification:	Other/General
Near Manufacturer:	Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454 USA
Representative:	William Jacques, Director of Regulatory and Quality
Authorized Representative:	Nova Biomedical GmbH Hessenring 13 A, Geb. G 64546 Mörfelden-Walldorf Germany Tel: +49 6105 4505-0
Conformity Assessment Route:	Annex III

Nova Biomedical, Inc. declares that the products listed are in conformity with the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices, including applicable essential requirements of Annex I for legal application of the CE Mark. All supporting documentation is retained under the premises of the manufacturer.

Nova Biomedical, Inc. declares that the electronic products listed are in conformity with the provisions of the Council Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Standards Applied:

EN ISO 13485:2016	**Medical devices. Quality management systems. Requirements for regulatory purposes**
EN ISO 14971:2012	**Medical devices – Application of risk management to medical devices**
EN 61010-1:2010	**Safety requirements for electrical equipment for measurement, control, and laboratory use -Part 1: General requirements**
EN 61010-2:101:2015	**Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment**

Signature: _____

William Jacques, Director of Regulatory and Quality

CE

Date: Jul/22/2020

List of Catalog items covered:

Catalog Number	Product Name	GMDN Number	Global Medical Device Nomenclature (GMDN) Name	DIMDI EDMS Code
14631	Power Cord Int 230V	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
38846	Nova Biomedical Capillary Tube Clot Catcher	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
38883	Stat Profile Critical Care Xpress Syringe Clot Catcher	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42032	Prime Sensor Card CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42033	Prime Sensor Card CCS Comp	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42043	Prime Reference Cartridge	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52484	Prime Pump Harness	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52582	Prime Probe S Line 100 ul	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52616	Prime Tubing L1 L2 L3	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52617	Prime Tubing Harness ABG/CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52669	Prime Safety Sample Port 5 Pk	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52703	Prime Acc Pack	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52856	Prime CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52857	Prime CCS Comp	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53418	Remanufactured Prime CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53420	Remanufactured Prime CCS Comp	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53656	Prime CCS w/Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53657	Prime CCS Comp w/Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53666	Remanufactured Prime CCS w/ Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53667	Remanufactured Prime CCS Comp w/ Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
55263	Prime Sensor Card CCS (High Volume)	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
55264	Prime Sensor Card CCS Comp (High Volume)	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42031	Prime Sensor Card ABG	56671	Point-of-Care blood gas analyzer IVD	21-02-02
52855	Prime ABG	56671	Point-of-Care blood gas analyzer IVD	21-02-02
53421	Remanufactured Prime ABG	56671	Point-of-Care blood gas analyzer IVD	21-02-02
53655	Prime ABG w/ Scanner	56671	Point-of-Care blood gas analyzer IVD	21-02-02
53665	Remanufactured Prime ABG w/ Scanner	56671	Point-of-Care blood gas analyzer IVD	21-02-02
55262	Prime Sensor Card ABG (High Volume)	56671	Point-of-Care blood gas analyzer IVD	21-02-02
25217	Linearity Standard Set A Levels 1,2,3,4 Multipack	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
55229	Nova Linearity Level 1,2,3,4	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
56198	Linearity Standard Set G Multipack	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-90-00

Catalog Number	Product Name	GMDN Number	Global Medical Device Nomenclature (GMDN) Name	DIMDI EDMS Code
45150	Prime Auto QC Cartridge CCS 200 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
52714	Prime Ampuled Control ABG/CCS	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
52864	Prime Auto QC Cartridge CCS 300 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53107	Prime Auto QC Cartridge ABG 200 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53108	Prime Auto QC Cartridge ABG 300 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53455	Prime Auto QC Cartridge CCS 100 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53456	Prime Auto QC Cartridge ABG 100 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
52427	Prime Calibrator Cartridge CCS Comp 300 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52861	Prime Calibrator Cartridge CCS Comp 100 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52862	Prime Calibrator Cartridge CCS 100 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52863	Prime Calibrator Cartridge CCS 300 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53104	Prime Calibrator Cartridge ABG 100 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53105	Prime Calibrator Cartridge CCS Comp 400 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53359	Prime Calibrator Cartridge ABG 300 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53360	Prime Calibrator Cartridge ABG 200 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53364	Prime Calibrator Cartridge CCS 200 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53365	Prime Calibrator Cartridge CCS Comp 200 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53463	Prime Calibrator Cartridge ABG 400 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53464	Prime Calibrator Cartridge ABG 500 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53465	Prime Calibrator Cartridge ABG 600 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53466	Prime Calibrator Cartridge CCS 400 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53467	Prime Calibrator Cartridge CCS 500 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53468	Prime Calibrator Cartridge CCS 600 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53469	Prime Calibrator Cartridge CCS Comp 500 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53470	Prime Calibrator Cartridge CCS Comp 600 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52865	Stat Profile Prime Calibrator Flush Fixture	56672	Point-of-Care blood gas/haemoximetry analyzer IVD	21-02-02

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Product Service

Certificate

No. Q5 120095 0001 Rev. 00

Holder of Certificate: **Hangzhou Tongzhou Biotechnology Co., Ltd.**
Room 102, Building 4, No. 191, Xintian Road, Yunhe Street
Linping District
311103 Hangzhou, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents, Control Material and Instruments for Clinical Chemistry, Immunochemistry (Immunology) and Infectious Diseases, including Professional Laboratory Use, Near Patient and Self Testing**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 120095 0001 Rev. 00

Report No.: SH23211001

Valid from: 2023-07-20
Valid until: 2026-07-19

Date, 2023-07-21

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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TÜV SÜD
Product Service

Certificate

No. Q5 120095 0001 Rev. 00

Applied Standard(s):

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

Facility(ies):

Hangzhou Tongzhou Biotechnology Co., Ltd.
Room 102, Building 4, No. 191, Xintian Road, Yunhe Street, Linping District, 311103 Hangzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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CMC MEDICAL DEVICES & DRUGS S.L.

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Hangzhou Tongzhou Biotechnology Co., Ltd
Room 102, Building 4, No. 191, Xintian Road, Yunhe Street, Linping District, Hangzhou, China.

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive/regulation and standard mention in Annex I of this certificate, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all below mentioned models of the medical device.

CE

Authorized Signature

Issue date: 06/04/2022

Expiration date: 25/01/2027

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CMC MEDICAL DEVICES

ANNEX I

Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Zopiclone (ZOP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Zolpidem (ZOL) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Zika NS1 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Zika IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Zika IgG/IgM and NS1 Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Vitamin D Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Vibrio cholerae O139 (VC O139) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Vibrio cholerae O1 (VC O1) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Vibrio cholerae O1/O139 Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Typhoid IgG/IgM Rapid Test(Whole Blood/Serum/ Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Typhoid IgG/IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Tuberculosis (TB) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
TSH Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Tricyclic Antidepressants (TCA) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Transferrin and FOB Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Tetanus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Syphilis Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Synthetic Marijuana (K2) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Streptococcus pneumoniae Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Strep B Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Strep A Rapid Test(Control Line in Red)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

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Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Strep A Rapid Test(Control Line in Blue)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
SP-10 Male Fertility Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Salmonella typhi Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
SAA Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
SAA and CRP Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
RSV&Influenza A+B Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
RSV Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Rotavirus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Rotavirus and Adenovirus Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Rheumatoid Factor Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Procalcitonin (PCT) Rapid Test (Whole Blood/Serum/ Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Procalcitonin (PCT) Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test Midstream	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test (Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test (Urine)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test (Serum/Plasma/Urine)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Phencyclidine (PCP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Oxycodone (OXY) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ovulation (LH) Rapid Test Midstream	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ovulation (LH) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Opiates (OPI) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
NT-proBNP Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

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Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Norovirus, Rotavirus, Adenovirus and Astrovirus Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Norovirus, Rotavirus and Adenovirus Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Norovirus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Myoglobin/CK-MB/Troponin I Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Myoglobin Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Mycoplasma Pneumoniae IgG/ IgM Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Mycoplasma pneumoniae Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Multi-Drugs Rapid Test Key Cup	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Multi-Drugs Rapid Test 1-Step Cup	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Multi-Drugs Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Morphine (MOP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
MONO Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Micro-Albumin Semi-Quantitative Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Micro-Albumin Qualitative Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Methylphenidate(MPD) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Methamphetamine (MET) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Methadone (MTD) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Marijuana (THC) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Malaria P.f./P.v. Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Malaria P.f./P.v. /Pan Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Malaria P.f./ Pan Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Malaria P.f. Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Lyme IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Leptospira IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

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Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Leishmania IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Lactoferrin Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ketamine (KET)Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Insulin-like Growth Factor-binding Protein 1 (iGFBP-1) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Influenza A+B Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Influenza A Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
IgE Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Human Semen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgM Rapid Test (Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgG/IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgG/IgM Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HEV IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HbA1c Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Hb+Hb-Hp Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H. pylori Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H. pylori Antibody Rapid Test(Whole Blood/Serum/ Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H. pylori Antibody Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H-FABP Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H-FABP and cTnI Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Gonorrhea Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
~~Gonorrhea and Chlamydia Combo Rapid Test~~	~~CLASS IVD OTHERS~~	~~IVD - Directive 98/79~~	~~RPS/215/2022~~	~~Yes~~
Giardia Lamblia Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
FSH Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
FOB Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

Issue date: 06/04/2022 **Expiration date: 25/01/2027**

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Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Filariasis IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Filariasis IgG/IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Fetal Fibronectin (fFN) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ferritin Semi-Quantitative Rapid test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ferritin Rapid test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Fentanyl (FYL) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ethyl Glucuronide (ETG) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Entamoeba/Giardia/Crypto Rapid Test (1 Window)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Entamoeba/Giardia/Crypto Combo Rapid Test (3 Windows)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Entamoeba histolytica Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ecstasy (MDMA) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Dengue NS1 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Dengue IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Dengue IgG/IgM and NS1 Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
D-dimer Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cryptosporidium Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cryptosporidium and Giardia Lamblia Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cotinine (COT) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cocaine (COC) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Clostridium difficile Toxin A +Toxin B Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Clostridium difficile GDH+ Toxin A +Toxin B Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Clostridium difficile GDH Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

Issue date: 06/04/2022

Expiration date: 25/01/2027

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

Verification Code

EC REP

CERTIFICATE

ECREP20220406.5

Ver: CERT-202110.V1

CERTIFICATE CERTIFICADO CERTIFIKAT CERTIFICAT 证书 자격증

Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
CK-MB Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Chikungunya IgG/IgM Rapid Test (Whole Blood/Serum/ Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Chikungunya IgG/IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Chagas Rapid Test(Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Chagas Rapid Test (Serum/ Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
CEA Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cardiac Troponin T (cTnT) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cardiac Troponin I (cTnI) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Candida albicans Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Campylobacter Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Calprotectin Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Calprotectin and Lactoferrin Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Calprotectin and FOB Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
CA19-9 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
CA15-3 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
CA125 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
C-reactive protein Semi-Quantitative Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
C-reactive protein Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Buprenorphine (BUP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Brucella Abortus Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Blood Stain Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Benzodiazepines (BZO) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Barbiturate (BAR) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Astrovirus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Amphetamine (AMP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

Issue date: 06/04/2022

Expiration date: 25/01/2027

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

Verification Code

EC REP

CERTIFICATE

ECREP20220406.5

Ver: CERT-202110.V1

Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
AMH Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
AFP Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Adenovirus&RSV Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Adenovirus, RSV and Influenza A+B Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Adenovirus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Adenovirus pneumoniae Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
7-Aminoclonazepam (7-ACL) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H-FABP and Myoglobin/CK-MB/Cardiac Troponin I Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

Issue date: 06/04/2022

Expiration date: 25/01/2027

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

Verification Code

CERTIFICATE CERTIFICADO CERTIFIKAT CERTIFICAT 证书 자격증

CE

DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer:	Hangzhou Tongzhou Biotechnology Co., Ltd.
Address:	Room 102, Building 4, No. 191, Xintian Road, Yunhe Street, Linping District, Hangzhou, China.
EC Representative:	CMC Medical Devices & Drugs S.L
Address:	C/Horacio Lengo № 18 CP 29006, Málaga-Spain
Product Name:	See attachments
Classification:	Others (IVDD)
Conformity Assessment Procedure:	Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Signature: 邵越水

Name/ Position: 邵越水/ Vice General Manager

Date: 2022.3.14

Place: Hangzhou / China

Attachment: Product List

No.	Product Description （产品名称）	CE Classification
1	Pregnancy (hCG) Rapid Test	Other
2	Pregnancy (hCG) Rapid Test (Urine)	Other
3	Pregnancy (hCG) Rapid Test Midstream	Other
4	Pregnancy (hCG) Rapid Test (Serum/Plasma/Urine)	Other
5	Pregnancy (hCG) Rapid Test (Whole Blood/Serum/Plasma)	Other
6	Ovulation (LH) Rapid Test	Other
7	Ovulation (LH) Rapid Test Midstream	Other
8	FSH Rapid Test	Other
9	AMH Rapid Test	Other
10	Fetal Fibronectin (fFN) Rapid Test	Other
11	Insulin-like Growth Factor-binding Protein 1 (iGFBP-1) Rapid Test	Other
12	HSV 1/2 IgM Rapid Test (Serum/Plasma)	Other
13	HSV 1/2 IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
14	HSV 1/2 IgG/IgM Rapid Test (Serum/Plasma)	Other
15	HSV 1/2 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
16	HSV 1/2 IgG/IgM Combo Rapid Test	Other
17	Candida albicans Rapid Test	Other
18	Gonorrhea Rapid Test	Other
19	Gonorrhea and Chlamydia Combo Rapid Test	Other
20	Strep B Rapid Test	Other
21	Adenovirus Rapid Test	Other
22	Rotavirus Rapid Test	Other
23	Norovirus Rapid Test	Other
24	Rotavirus and Adenovirus Combo Rapid Test	Other
25	Norovirus, Rotavirus and Adenovirus Combo Rapid Test	Other
26	Astrovirus Rapid Test	Other
27	Norovirus, Rotavirus, Adenovirus and Astrovirus Combo Rapid Test	Other
28	Entamoeba histolytica Rapid Test	Other
29	Giardia Lamblia Rapid Test	Other
30	Cryptosporidium Rapid Test	Other
31	Cryptosporidium and Giardia Lamblia Combo Rapid Test	Other
32	Entamoeba/Giardia/Crypto Rapid Test (1 Window)	Other
33	Entamoeba/Giardia/Crypto Combo Rapid Test (3 Windows)	Other
34	Campylobacter Rapid Test	Other
35	Clostridium difficile GDH Rapid Test	Other
36	Clostridium difficile Toxin A +Toxin B Combo Rapid Test	Other
37	Clostridium difficile GDH+ Toxin A +Toxin B Combo Rapid Test	Other
38	H. pylori Antibody Rapid Test (Serum/Plasma)	Other
39	H. pylori Antibody Rapid Test (Whole Blood/Serum/Plasma)	Other
40	H. pylori Antigen Rapid Test	Other
41	Vibrio cholerae O1 (VC O1) Rapid Test	Other
42	Vibrio cholerae O139 (VC O139) Rapid Test	Other
43	Vibrio cholerae O1/O139 Combo Rapid Test	Other
44	Chagas Rapid Test (Serum/Plasma)	Other
45	Chagas Rapid Test (Whole Blood/Serum/Plasma)	Other
46	Chikungunya IgG/IgM Rapid Test (Serum/Plasma)	Other
47	Chikungunya IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
48	Dengue IgG/IgM Rapid Test	Other
49	Dengue NS1 Rapid Test	Other
50	Dengue IgG/IgM and NS1 Combo Rapid Test	Other
51	Zika NS1 Rapid Test	Other
52	Zika IgG/IgM Rapid Test	Other
53	Zika IgG/IgM and NS1 Combo Rapid Test	Other

54	Filariasis IgG/IgM Rapid Test (Serum/Plasma)	Other
55	Filariasis IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
56	Typhoid IgG/IgM Rapid Test (Serum/Plasma)	Other
57	Typhoid IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
58	Salmonella typhi Antigen Rapid Test	Other
59	Leishmania IgG/IgM Rapid Test	Other
60	Leptospira IgG/IgM Rapid Test	Other
61	Malaria P.f. Rapid Test	Other
62	Malaria P.f./ Pan Rapid Test	Other
63	Malaria P.f./P.v. Rapid Test	Other
64	Malaria P.f./P.v. /Pan Rapid Test	Other
65	HEV IgG/IgM Rapid Test	Other
66	Syphilis Rapid Test	Other
67	Strep A Rapid Test (Control Line in Red)	Other
68	Strep A Rapid Test (Control Line in Blue)	Other
69	Streptococcus pneumoniae Antigen Rapid Test	Other
70	Mycoplasma pneumoniae Antigen Rapid Test	Other
71	Mycoplasma Pneumoniae IgG/IgM Combo Rapid Test	Other
72	MONO Rapid Test	Other
73	Adenovirus pneumoniae Antigen Rapid Test	Other
74	Influenza A+B Rapid Test	Other
75	Influenza A Rapid Test	Other
76	RSV Rapid Test	Other
77	RSV&Influenza A+B Combo Rapid Test	Other
78	Adenovirus&RSV Combo Rapid Test	Other
79	Adenovirus, RSV and Influenza A+B Combo Rapid Test	Other
80	Brucella Abortus Antigen Rapid Test	Other
81	Lyme IgG/IgM Rapid Test	Other
82	Tetanus Rapid Test	Other
83	Tuberculosis (TB) Rapid Test	Other
84	7-Aminoclonazepam (7-ACL) Rapid Test	Other
85	Amphetamine (AMP) Rapid Test	Other
86	Barbiturate (BAR) Rapid Test	Other
87	Buprenorphine (BUP) Rapid Test	Other
88	Benzodiazepines (BZO) Rapid Test	Other
89	Cocaine (COC) Rapid Test	Other
90	Cotinine (COT) Rapid Test	Other
91	Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test	Other
92	Ethyl Glucuronide (ETG) Rapid Test	Other
93	Fentanyl (FYL) Rapid Test	Other
94	Ketamine (KET)Rapid Test	Other
95	Ecstasy (MDMA) Rapid Test	Other
96	Methamphetamine (MET) Rapid Test	Other
97	Morphine (MOP) Rapid Test	Other
98	Methylphenidate (MPD) Rapid Test	Other
99	Methadone (MTD) Rapid Test	Other
100	Opiates (OPI) Rapid Test	Other
101	Oxycodone (OXY) Rapid Test	Other
102	Phencyclidine (PCP) Rapid Test	Other
103	Synthetic Marijuana (K2) Rapid Test	Other
104	Tricyclic Antidepressants (TCA) Rapid Test	Other
105	Marijuana (THC) Rapid Test	Other
106	Zolpidem (ZOL) Rapid Test	Other
107	Zopiclone (ZOP) Rapid Test	Other
108	Multi-Drug Rapid Test	Other
109	Multi-Drug Rapid Test 1-Step Cup	Other
110	Multi-Drug Rapid Test Key Cup	Other
111	AFP Rapid Test	Other

112	CEA Rapid Test	Other
113	CA125 Rapid Test	Other
114	CA15-3 Rapid Test	Other
115	CA19-9 Rapid Test	Other
116	FOB Rapid Test	Other
117	Calprotectin and FOB Combo Rapid Test	Other
118	Transferrin and FOB Combo Rapid Test	Other
119	Hb+Hb-Hp Combo Rapid Test	Other
120	Cardiac Troponin I (cTnI) Rapid Test	Other
121	Cardiac Troponin T (cTnT) Rapid Test	Other
122	CK-MB Rapid Test	Other
123	Myoglobin Rapid Test	Other
124	H-FABP Rapid Test	Other
125	H-FABP and cTnI Combo Rapid Test	Other
126	Myoglobin/CK-MB/Troponin I Combo Rapid Test	Other
127	H-FABP and Myoglobin/CK-MB/Cardiac Troponin I Combo Rapid Test	Other
128	NT-proBNP Rapid Test	Other
129	D-dimer Rapid Test	Other
130	C-reactive protein Rapid Test	Other
131	C-reactive protein Semi-Quantitative Rapid Test	Other
132	Procalcitonin (PCT) Rapid Test (Serum/Plasma)	Other
133	Procalcitonin (PCT) Rapid Test (Whole Blood/Serum/Plasma)	Other
134	Ferritin Rapid Test	Other
135	Ferritin Semi-Quantitative Rapid Test	Other
136	SP-10 Male Fertility Rapid Test	Other
137	TSH Rapid Test	Other
138	Vitamin D Rapid Test	Other
139	HbA1c Rapid Test	Other
140	Blood Stain Rapid Test	Other
141	Human Semen Rapid Test	Other
142	Calprotectin Rapid Test	Other
143	Lactoferrin Rapid Test	Other
144	Calprotectin and Lactoferrin Combo Rapid Test	Other
145	IgE Rapid Test	Other
146	Rheumatoid Factor Rapid Test	Other
147	Micro-Albumin Semi-Quantitative Rapid Test	Other
148	Micro-Albumin Qualitative Rapid Test	Other
149	SAA Rapid Test	Other
150	SAA and CRP Combo Rapid Test	Other

BORSE EMERGENZA SMART

POLIESTERE RIVESTITO IN PVC

27153 27152 27150

Tracolle incluse con le borse grandi/medie

4 tasche (5 per 27153) 1 o 2 frontali, 2 laterali e 1 sul retro

27153

TELA CERATA DI PVC

27157 27158 27155

Ampia tasca superiore e tracolle incluse con le borse medie

Fodera estraibile e facile da pulire

Ampia tasca superiore

27157

Fondo e tasca anteriore imbottiti

Anello di sicurezza metallico

Zip10 mm

Fondo in gomma con piedini

Tracolle

BORSE SMART: poliestere rivestito in PVC o tela cerata di PVC - vuote
Borse emergenza professionali molto capienti grazie alla modularità interna che consente un'organizzazione personalizzata degli spazi. Fornite di tasche esterne, divisori interni e una borsa staccabile (2 per cod. 27153) con finestra trasparente. Esterno in poliestere 600D rivestito in PVC, resistente all'acqua, o esterno in tela cerata di PVC (27155-8), resistente al freddo. Tutte le borse hanno l'interno in poliestere 600D rivestito in PVC. Provviste di doppia striscia gialla rifrangente. Sfoderabili per una facile pulizia. Fondo in gomma impermeabile per evitare infiltrazioni di acqua.

Materiale esterno		Modello	Colore	Misura	Spazi interni modulari	Tasche esterne
Poliestere rivestito PVC	PVC					
27150	27155	Piccolo	rosso	45x28xh 28 cm	3	4
27151	-	Medio	rosso	55x35xh 32 cm	6	4
-	27157	Medio	rosso	55x35xh 38 cm	6	5
27152	-	Medio	blu	55x35xh 32 cm	6	4
-	27158	Medio	nero	55x35xh 38 cm	6	5
27153	-	Grande	rosso	65x35xh 35 cm	6	5

BORSE DI EMERGENZA

POLIESTERE RIVESTITO IN PVC

TELA CERATA DI PVC

27165 27167 27166

2 tasche laterali 22x18 cm e 11x18 cm

27167

Tasca laterale 32x18 cm

Tasca frontale 35x20 cm

- **27165 BORSA EMERGENZA - poliestere - rossa - 35x45xh 21 cm**
- **27166 BORSA EMERGENZA - PVC - rossa - 35x45xh 21 cm**
- **27167 BORSA EMERGENZA - PVC - blu - 35x45xh 21 cm**

Borse estremamente capienti dalle dimensioni compatte. Ampio scomparto centrale, 1 tasca frontale e 3 laterali. Possibilità di essere trasportate a spalla (tracolla) o a mano (2 maniglie).Materiale robusto e resistente all'acqua: poliestere 600D rivestito in PVC (27165) o tela cerata di PVC (27166-7). Provviste di strisce gialle rifrangenti e fondo in gomma.

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

Certificate Holder: **MACHEREY-NAGEL GmbH & Co. KG**
Valencienner Str. 11
52355 Düren
Germany

including the locations according to annex

Scope: Design, development, production and distribution of products for filtration, rapid tests, water analysis, bioanalysis and chromatography, as well as service and administration.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2023-05-29 until 2026-05-28.

2023-04-18

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

No.	Location	Scope
/01	c/o MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design, development, production and distribution of products for filtration, rapid tests, and water analysis, as well as service and administration
/02	c/o MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design, development and production of products for bioanalysis and chromatography
/04	c/o MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Storage

2023-04-18

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

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

Scope: Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine and gastric fluid analysis, as well as in vitro diagnostic products for bioanalytical sample preparation.

(see attachment for sites included)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1127255-40
Effective date: 2023-05-29
Expiry date: 2026-05-28
Issue date: 2023-04-12

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Irene Carraretto
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

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

The scope of certification covers the following sites:

No.	Facility	Scope
/01	c/o MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine and gastric fluid analysis, as well as in vitro diagnostic products for bioanalytical sample preparation.
/02	c/o MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design and development, manufacture and quality control of in vitro diagnostic products for bioanalytical sample preparation.
/03	c/o MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 1127255-40
Effective date: 2023-05-29
Expiry date: 2026-05-28
Issue date: 2023-04-12

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Irene Carraretto
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HX 1038121-1

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

EUDAMED Single Registration No.: DE-MF-000005636

Products: Products of class B:

CLINICAL CHEMISTRY
IVR 608: Devices intended to be used for screening, determination or monitoring of physiological markers
W01010602 URINE TESTING (CC) - RT & POC

Products of class B, for near-patient testing:

CLINICAL CHEMISTRY
IVR 608: Devices intended to be used for screening, determination or monitoring of physiological markers
W01010602 URINE TESTING (CC) - RT & POC
W01010699 CLIN. CHEM. RT & POC - OTHER

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. If class B, C or D devices for self-testing or near-patient testing are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.1 is required before placing them on the market. If companion diagnostics are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.2 is required before placing them on the market. If class D devices are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.10 is required before placing them on the market.

Report No.: 1085166-80

Effective date: 2023-05-16

Expiry date: 2028-05-15

Issue date: 2023-05-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-IVDR-097

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning in vitro diagnostic medical devices with the identification number 0197.

EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices,
Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HX 1038121-1

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

Products of class B, for self-testing:

CLINICAL CHEMISTRY
IVR 608: Devices intended to be used for screening, determination or monitoring of physiological markers
W01010602 URINE TESTING (CC) - RT & POC

Products of class C, for self-testing:

CLINICAL CHEMISTRY
IVR 608: Devices intended to be used for screening, determination or monitoring of physiological markers
W01010602 URINE TESTING (CC) - RT & POC

Authorised representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-05-16

Report No.: 1085166-80

Effective date: 2023-05-16

Expiry date: 2028-05-15

Issue date: 2023-05-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-IVDR-097

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning in vitro diagnostic medical devices with the identification number 0197.

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
И СОЦИАЛЬНОГО РАЗВИТИЯ

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

№ ФСР 2009/05681

от **15 сентября 2009 года** Срок действия: **не ограничен.**

Настоящее удостоверение выдано

ЗАО "Термо Фишер Сайентифик",
Россия, 196240, Санкт-Петербург, ул. Кубинская, д.73, корпус 1, лит.А

и подтверждает, что изделие медицинского назначения
(изделие медицинской техники)

Дозаторы пипеточные, одно- и многоканальные, "Блэк"
по ТУ 9443-008-33189998-2009

производства

ЗАО "Термо Фишер Сайентифик",
Россия, 196240, Санкт-Петербург, ул. Кубинская, д.73, корпус 1, лит.А

класс потенциального риска **2а** ОКП **94 4370**

соответствующее комплекту регистрационной документации

КРД № 33014 от 09.07.2009

приказом Росздравнадзора **от 15 сентября 2009 года № 7252-Пр/09**

разрешено к производству, продаже и применению на территории Российской Федерации

Руководитель Федеральной службы
по надзору в сфере здравоохранения
и социального развития **Н.В. Юргель**

006376

Бланк изготовлен ЗАО «ОПЦИОН» (лицензия № 05-05-09/003 ФНС РФ, уровень В), договор РД № 08/63, тел. (495) 648 6068, 608 7617, г. Москва, 2008 г.

EMERGENCY BAG - red

Code: 27165

Category: Nylon bags and rucksacks

Unit of sale: 1 pc.

Minimum order: 1

Type: No medical device

EAN13: 8023279271652

Description:

EMERGENCY BAG - polyester - red - 35x45xh 21 cm

Capacious bag, despite the compact size. Large central compartment, 1 front and 3 lateral pockets.
May be carried on shoulder (braces) or hand (2 handles).
Made of strong, water resistant material 600D polyester PVC coated.
Provided with yellow reflective strips and rubber bottom.

2 lateral pockets 22x18 cm and 11x18 cm
Lateral pocket 32x18 cm
Front pocket 35x20 cm