Certificate of Registration

This certificate has been awarded to

AO Vector-Best

3, Pasechnaya str., Novosibirsk, 630117, Russian Federation

in recognition of the organization's Quality Management System which complies with

ISO 13485:2016

The scope of activities covered by this certificate is defined below

Design, Development, and Production of In Vitro Diagnostic Medical Devices (ELISA, PCR)

Certificate Number **209535/A/0003/UK/En**

A certificate number of 0001, confirms the Client has a single site Certified & the site is their Head Office or Main site in relation to the Certified scope with URS. A certificate number of 0002, or greater (e.g.: xxxx/B/0002/UK/En) refers to a client that has more than one site certified with URS, as such, the following statement shall apply - 'The validity of this certificate depends on the validity of the main certificate'.

Date of Issue of Certification Cycle	Issue Number	Certificate Expiry Date	Certification Cycle
05 October 2022	1	04 October 2025	1
Revision Date	**Revision Number**	**Original Certificate Issue Date**	**Scheme Number**
06 October 2022	1	05 October 2022	n/a

For detailed explanation for the data fields above, refer to http://www.urs-holdings.com/logos-and-regulations

Issued by *On behalf of the Schemes Manager*

EC DECLARATION OF CONFORMITY

ZAO "Vector-Best" hereby ensures under own responsibility and declares that the products listed on pages 2-4 are in conformity with applicable provisions and fulfill the essential requirements of Annex I Directive 98/79/EC of 27 October 1998 regarding in vitro diagnostic medical devices.

Classification of products: Other devices (all devices except Annex II and self-testing devices)

Conformity assessment procedure: Annex III (not including section 6).

Manufacturer: ZAO "Vector-Best"
Address: AHC, Koltsovo,
Novosibirsk Region, 630559, Russia,
Tel. +7 (383) 363 20 60,
Fax: +7 (383) 363 35 55

European authorized representative: Bioron GmbH,
Rheinhorststr. 18, D-67071
Ludwigshafen, Germany.
tel.: +49 (0) 621 5720 915,
fax: +49 (0) 621 5720 916

Date: 2013/04/12

Murat Khusainov
General Director ZAO «Vector-Best»

No.	Product name	Identification data	REF
1.	Vectohep A-IgM	ELISA kit for determination of IgM to hepatitis A virus	D-0352
2.	Vectohep A-IgG	ELISA kit for quantitative and qualitative determination of IgG to hepatitis A virus	D-0362
3.	Vectohep TTV-IgG	ELISA kit for determination of IgG to TT virus	D-0802
4.	Vectohep E-IgG	ELISA kit for determination of IgG to hepatitis E virus	D-1056
5.	Vectohep E-IgM	ELISA kit for determination of IgM to hepatitis E virus	D-1058
6.	Vectohep G-IgG	ELISA kit for determination of IgG to hepatitis G virus	D-1252
7.	LymeBest-IgG	ELISA kit for determination of IgG to infectious borreliosis agents	D-1452
8.	LymeBest-IgM	ELISA kit for determination of IgM to infectious borreliosis agents	D-1454
9.	RecombiBest antipallidum-IgG	ELISA kit for determination of IgG to Treponema pallidum	D-1852
10.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1856
11.	RecombiBest antipallidum-IgM	ELISA kit for determination of IgM to Treponema pallidum	D-1858
12.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1857
13.	VectoHSV-1,2 - IgG	ELISA kit for determination of IgG to herpes simplex virus types 1 and 2	D-2152
14.	VectoHSV - IgM	ELISA kit for determination of IgM to herpes simplex virus types 1 and 2	D-2154
15.	VectoHHV-8 - IgG	ELISA kit for determination of IgG to human herpes virus type 8	D-2160
16.	VectoHHV-6 - IgG	ELISA kit for determination of IgG to human herpes virus type 6	D-2166
17.	Ureaplasma urealyticum – IgG-EIA-BEST	ELISA kit for determination of IgG to Ureaplasma urealyticum antigens	D-2254
18.	Ureaplasma urealyticum – IgA-EIA-BEST	ELISA kit for determination of IgA to Ureaplasma urealyticum antigens	D-2258
19.	VectoParotitis-IgG	ELISA kit for determination of IgG to parotitis virus	D-2602
20.	VectoParotitis-IgM	ELISA kit for determination of IgM to parotitis virus	D-2604
21.	Toxocara-IgG-EIA-BEST	ELISA kit for determination of IgG to toxocara antigens	D-2752
22.	Opisthorchiasis – IgG-EIA-BEST	ELISA kit for determination of IgG to opisthorchiasis antigens	D-2952
23.	Echinococcus-IgG-EIA-BEST	ELISA kit for determination of IgG to Echinococcus	D-3356

		antigens	
24.	Ascarid-IgG-EIA-BEST	ELISA kit for determination of IgG to Ascaris lumbricoides	D-3452
25.	Lamblia-antibodies-EIA-BEST	ELISA kit for determination of IgG, IgM and IgA to Lamblia antibodies	D-3552
26.	Lamblia-IgM-EIA-BEST	ELISA kit for determination of IgM to Lamblia antibodies	D-3554
27.	Lamblia-antigen-EIA-BEST	ELISA kit for determination of Lamblia antigen	D-3556
28.	Helicobacter pylori-CagA-antigen-EIA-BEST	ELISA kit for determination of total antibodies to CagA Helicobacter pylori	D-3752
29.	TSH-EIA-BEST	ELISA kit for determination of concentration of thyroid-stimulating hormone	X-3952
30.	T3 total-EIA-BEST	ELISA kit for determination of concentration of total triiodothyronine	X-3954
31.	T4 total-EIA-BEST	ELISA kit for determination of concentration of total thyroxine	X-3956
32.	Anti-TPO-EIA-BEST	ELISA kit for determination of antibody concentration to thyroperoxidase	X-3968
33.	PAPP-A-EIA-BEST	ELISA kit for determination of concentration of pregnancy-associated plasma protein A	D-4160
34.	Mycoplasma hominis-IgG-EIA-BEST	ELISA kit for determination of IgG to Mycoplasma hominis	D-4352
35.	Mycoplasma hominis-IgA-EIA-BEST	ELISA kit for determination of IgA to Mycoplasma hominis	D-4358
36.	Mycoplasma pneumoniae-IgG-EIA-BEST	ELISA kit for determination of IgG to Mycoplasma pneumoniae	D-4362
37.	Mycoplasma pneumoniae-IgM-EIA-BEST	ELISA kit for determination of IgM to Mycoplasma pneumoniae	D-4366
38.	Vectocrimean – CHF – IgG	ELISA kit for determination of IgG to Crimean-Congo hemorrhagic fever virus	D-5052
39.	Vectocrimean – CHF – IgM	ELISA kit for determination of IgM to Crimean-Congo hemorrhagic fever virus	D-5054
40.	CEA-EIA-BEST	ELISA kit for determination of concentration of carcinoembryonic antigen	T-8454
41.	AFP-EIA-BEST	ELISA kit for determination of concentration of Alpha-Fetal Protein	T-8456
42.	CA-125-EIA-BEST	ELISA kit for determination of concentration of oncomarker CA-125	T-8466
43.	CA 19-9-EIA-BEST	ELISA kit for determination of concentration of CA 19-9	T-8470
44.	CA 15-3-EIA-BEST	ELISA kit for determination of concentration of oncomarker CA 15-3	T-8472
45.	NSE-EIA-BEST	ELISA kit for determination of concentration of neuron specific enolase	T-8476

46.	Ferritin-EIA-BEST	ELISA kit for determination of concentration of ferritin	T-6552
47.	IgE total-EIA-BEST	ELISA kit for determination of concentration of total IgE	A-8660
48.	IgG total-EIA-BEST	ELISA kit for determination of concentration of total IgG	A-8662
49.	IgM total-EIA-BEST	ELISA kit for determination of concentration of total IgM	A-8664
50.	IgA total-EIA-BEST	ELISA kit for determination of concentration of total IgA	A-8666
51.	Gamma-Interferon-EIA-BEST	ELISA kit for determination of concentration of gamma-interferon	A-8752
52.	Interleukine-4-EIA-BEST	ELISA kit for determination of concentration of Interleukine-4	A-8754
53.	Alpha-TNF-EIA-BEST	ELISA kit for determination of concentration of alpha-tumor necrosis factor	A-8756
54.	Alpha-Interferon-EIA-BEST	ELISA kit for determination of concentration of alpha-interferon	A-8758
55.	Interleukine-6-EIA-BEST	ELISA kit for determination of concentration of Interleukine-6	A-8768
56.	Interleukine-2-EIA-BEST	ELISA kit for determination of concentration of Interleukine-2	A-8772
57.	Procalcitonin-EIA-BEST	ELISA kit for determination of concentration of procalcitonin	A-9004
58.	NTproBNP-EIA-BEST	ELISA kit for determination of concentration of N-terminal prohormone of brain natriuretic peptide	A-9102
59.	Troponin I-EIA-BEST	ELISA kit for determination of concentration of troponin I	A-9106

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

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-09H46

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

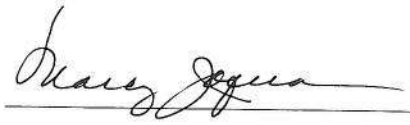
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H46-02	58236	CELL-DYN Emerald CLEANER	**Self-declared**
09H47-02	61165	CELL-DYN Emerald CN-FREE LYSE	**Self-declared**
09H48-02	58237	CELL-DYN Emerald 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
Harmonized Standards	Listed in the Technical Documentation

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

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

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	02-Dec-2015	Date of Approval:	01 DEC 2015
Date Issued:	DEC 02 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V6 July 6, 2015	Effective (Date or Lot Number):	DEC 03 2015

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- 0511 DC DOI 2013/08 (3)

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
5376	Clauss Fibrinogen 100	55997
5376H	Clauss Fibrinogen 100	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

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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

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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

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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- 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

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

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

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

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

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

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

TÜV®

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ECREP20220406.5

Ver: CERT-202110.V1

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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

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

Verification Code

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Ver: CERT-202110.V1

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

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

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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

Issue date: 06/04/2022

Expiration date: 25/01/2027

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CMC MEDICAL DEVICES

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

Issue date: 06/04/2022

Expiration date: 25/01/2027

CMC Medical Devices & Drugs S.L.
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www.cmcmedicaldevices.com

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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**

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
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Ver: CERT-202110.V1

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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

ООО «ОВЕСТ»

Юридический адрес: Россия, 302006, г. Орел
ул. Московская, 98 пом. 4

ПАСПОРТ КАЧЕСТВА № 165

Дата изготовления – апрель-май 2024 г

Дата выдачи паспорта 5 июня 2024 г.

Ерш пробирочный (искусственная щетина) 280х100х25

ТУ 9677-004-11976371-03 **ОКП 96 7762**

Тип: А-1

Количество: 15000 шт .

Контроль показателей качества:

Наименование контролируемых показателей	Норма по ТУ	Заключение
Общая длина	260 мм-280 мм	Выдерживают
Длина рабочей части	60-70 мм,но не более 100 мм	Выдерживают
Диаметр рабочей части	22мм- 25 мм	Выдерживают

Гарантийный срок хранения – 12 месяцев с момента отгрузки потребителю.

Заключение: Данная продукция соответствует обязательным требованиям ТУ.

Ответственный за приемку _____

М.П.

Certificate DE22/00000148

The management system of

ams-OSRAM AG

Tobelbader Strasse 30, Schloß Premstätten, AT 8141 Premstätten

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Research and development, design, production and sales of sensor solutions, ICs and related software, pre-materials, equipment, opto semiconductor and lighting products, services and components for sensing, illumination and visualization

This certificate is valid from 15 November 2023 until 06 March 2026 and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 20 July 2022

Organization certified since 28 September 2001 and first certified by SGS on 20 July 2022.

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by

Jonathan Hall

Global Head - Certification Services

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - www.sgs.com

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

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

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

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

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

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

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

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

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

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

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 2022.12.14

General Manager

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

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

RUSSIAN FEDERATION

№ 0101475

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«ПРОМТЕХСТАНДАРТ»

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации
ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

ИСО 13485

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер РОСС RU.32001.04ИБФ1.ОС33.17919

Срок действия с 21.03.2022 по 20.03.2025

ОРГАН ПО СЕРТИФИКАЦИИ
№ РОСС RU.32001.04ИБФ1.ОС33
ООО «Научно-исследовательский институт проектирования и измерений»
141730, Московская область, город Лобня, улица Борисова, дом 14, корпус 2, помещение 006, офис 1

ВЫДАН
Общество с ограниченной ответственностью «МИНИМЕД»
ИНН: 3234007127 ОГРН: 1023202138332
Адрес: 241520, Брянская обл, Брянский р-н, село Супонево, ул Шоссейная, зд 17А

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА

применительно к видам работ согласно приложению №1 к настоящему сертификату

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ СТАНДАРТА

ГОСТ ISO 13485-2017(ISO 13485:2016)

Выдан на основании решения экспертной комиссии,
протокол РОСС RU.32001.04ИБФ1.ОС33.17919П от 21.03.2022

Проверка подлинности сертификата соответствия

ООО «НИИ ПИ»

Руководитель органа _____ (подпись) К.Р. Василенко (инициалы, фамилия)

Эксперт _____ (подпись) М.Т. Антипин (инициалы, фамилия)

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ (услуг) в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2020 г., «В», ТЗ № 974.

RUSSIAN FEDERATION

№ 0101474

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «ПРОМТЕХСТАНДАРТ»

№ РОСС RU.32001.04ИБФ1 в едином реестре зарегистрированных систем добровольной сертификации

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

ПромТех Стандарт

ИСО 13485

ПРИЛОЖЕНИЕ № 1

К сертификату соответствия № РОСС RU.32001.04ИБФ1.ОС33.17919
(является неотъемлемой частью сертификата соответствия)

Срок действия с 21.03.2022 по 20.03.2025

ОРГАН ПО СЕРТИФИКАЦИИ

№ РОСС RU.32001.04ИБФ1.ОС33

ООО «Научно-исследовательский институт проектирования и измерений»

141730, Московская область, город Лобня, улица Борисова, дом 14, корпус 2, помещение 006, офис 1

Применительно к видам работ: Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики.

ООО «НИИ ПИ»

Руководитель органа _____ (подпись) К.Р. Василенко (инициалы, фамилия)

Эксперт _____ (подпись) М.Т. Антипин (инициалы, фамилия)

Настоящий сертификат соответствия обязывает организацию поддерживать состояние выполняемых работ (услуг) в соответствие с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации системы добровольной сертификации «ПромТехСтандарт» и подтверждаться при прохождении ежегодного инспекционного контроля

АО «ОПЦИОН», Москва, 2020 г., «Б», тз № 974.

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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Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

Additional site: 2325 SW Martin Highway, Palm City, Florida 34990 USA

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The design, development, manufacture, distribution, installation and service of IVDD General Laboratory Instruments.

Main site: Management, QA, Design, Sales, Service

Additional site: Manufacturing, Quality Control, Distribution, Shipping, Installation and Service.

Certificate Number:
9362

Revision Level: 09

Initial Certification Date:
March 28, 2012

Date of Certification Decision:
December 19, 2023

Issuing Date:
December 19, 2023

Valid Until:
December 18, 2026

ISO 13485:2016 CERTIFICATION ™

SCC Accredited CB-MS OCSM Accrédité CCN ™

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intertek

Calin Moldovean
President

Intertek Testing Services NA Inc. dba Intertek,
900 Chelmsford Street,
Lowell, MA, USA