Digitally signed by Ceaicovschi Tudor
Date: 2025.02.28 18:18:32 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
Effective Date: 2024-04-14
Latest Revision Date: 2024-03-26
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-7-0664DC 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

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

ELITechGroup Inc.
370 West 1700 South
Logan
Utah
84321
USA

Facility ID Number: F000174

Holds Certificate No: **MDSAP 689350**

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

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

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

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

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

...making excellence a habit.™

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 GMED GROUPE LNE

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

Current issue date: 22 June 2024
Expiry date: 21 June 2027
Certificate identity number: 10598757

Original approval(s):
ISO 13485 - 9 June 2019

Certificate of Approval

This is to certify that the Management System of:

VitalScientific B.V.

also trading as: **ELITechGroup**

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00020722

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:
Design, development and manufacturing of clinical chemistry analyzers and contract manufacturing of ion-selective electrodes (ISE) and erythrocyte sedimentation rate (ESR) analyzers.

Paul Graaf

Area Operations Manager, Europe

Issued by: LRQA Limited

UKAS MANAGEMENT SYSTEMS 0001

Certificate Schedule

Location	Activities
VitalScientific B.V. also trading as: **ELITechGroup** Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers and contract manufacturing of ion-selective electrodes (ISE) and erythrocyte sedimentation rate (ESR) analyzers.
VitalScientific B.V. also trading as: **ELITechGroup** Kanaaldijk 90, 6956 AX Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers and contract manufacturing of ion-selective electrodes (ISE) and erythrocyte sedimentation rate (ESR) analyzers.

UKAS MANAGEMENT SYSTEMS 0001

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.

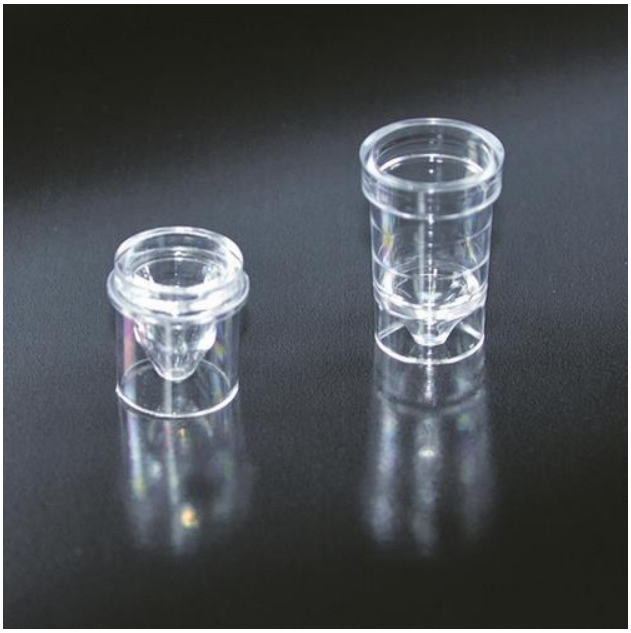
ELITechGroup B.V.

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				✓	

TECHNICAL DATA SHEET



CE

CENTRIFICHEM® SAMPLE CUPS

Multi-purpose sample cups with excellent optical properties. Material: polystyrene.

Cod.	Vol. ml	Dim. mm	Compatibility
1024/V	0.25	Ø 14x16	CentrifiChem®, Beckman® Synchron® and similar.
1022/V	2	Ø 16x24	Beckman® Access®, Hyland Laser Beam Analyzer, IL - Instrumentation Laboratory® ACL®, Olympus® AU400 / AU600 / AU640 / AU2700 / AU5400, Sysmex® CA 540 and similar.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Medica Corporation

(FIN F002402)

Main Site: 5 Oak Park Drive, Bedford, Massachusetts, 01730, United States

Additional Site: 3 Oak Park Drive, Bedford, Massachusetts, 01730, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

Design, Development, Manufacture, Service, Installation and Distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, in-vitro diagnostic analyzers/software used in diagnosis and management of cancer, immune status, disease status, autoimmune status, cardiac markers, protein metabolism, endocrine disorders, blood analytes, urinalysis, blood gases.

Certificate Number:
0089217-01

Initial Certification Date:
2019-04-19

Date of Certification Decision:
2022-03-24

Certification Effective Date:
2022-04-18

Certification Expiry Date:
2025-04-18

ISO 13485:2016 CERTIFICATION™

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851

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

Products For Health Care

Declaration of Conformity CE

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

Manufacturer

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

Representative

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

Means of Conformity

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

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

Signature:

Name: Photios Makris

Title: Director of Regulatory Affairs

EasyBloodGas and EasyStat Accessories

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

EasyElectrolyte Accessories

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

EasyLyte Accessories

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

EasyLyte Accessories, continued

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

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

Declaration of Conformity CE

Product Name:

EasyLyte Analyzer and accessories per attachment

Model/Type:

Na/K, Na/K/Cl, Na/K/Li,
Na/K/Cl/Li, Na/K/Ca/pH,
Na/K/Cl/Ca/Li

Manufacturer

Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA
Single Registration Number (SRN): US-MF-000037250

Representative

EC REP Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are covered by Annex III of Directive 98/79/EC. These products are self-certified since they are for professional use only and are not listed on Annex II, List A or Annex II, List B of Directive 98/79/EC. In addition, they are in conformity with the Annex I, “Essential Requirements” and provisions of council Directive 98/79/EC for In Vitro Diagnostic Medical Devices, Directive 2011/65/EU Restriction of Hazardous Substance in Electrical and Electronic Equipment, and their corresponding amendments.

Place and Date: Bedford, Massachusetts, USA, 26 May 2022

Signature:

Name: Photios Makris, Ph.D.
Title: VP, Regulatory Affairs

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Catalog No.	EasyLyte Analyzer and Accessories	EDMA Code	Class
2004	EasyLyte Analyzer, Na/K	21 07 11 02	General IVD device, not listed in IVDD Annex II and not intended for self-testing
2014	EasyLyte Analyzer, Na/K/Cl	21 07 11 02	
2015	EasyLyte Analyzer, Na/K/Li	21 07 11 02	
2016	EasyLyte Analyzer, Na/K/Ca/pH	21 07 11 02	
2021	EasyLyte Analyzer, Na/K/Cl/Li	21 07 11 02	
2030	EasyLyte Analyzer, Na/K/Cl/Ca/Li	21 07 11 02	
C2004	EasyLyte Analyzer, Na/K	21 07 11 02	
C2014	EasyLyte Analyzer, Na/K/Cl	21 07 11 02	
C2015	EasyLyte Analyzer, Na/K/Li	21 07 11 02	
C2016	EasyLyte Analyzer, Na/K/Ca/pH	21 07 11 02	
C2030	EasyLyte Analyzer, Na/K/Cl/Ca/Li	21 07 11 02	
L2014	EasyLyte Analyzer, Na/K/Cl	21 07 11 02	
L2015	EasyLyte Analyzer, Na/K/Li	21 07 11 02	
L2016	EasyLyte Analyzer, Na/K/Ca/pH	21 07 11 02	
L2021	EasyLyte Analyzer, Na/K/Cl/Li	21 07 11 02	
2101	EasyLyte K+ Electrode	11 04 01 06	
2102	EasyLyte Na+ Electrode	11 04 01 07	
2103	EasyLyte Reference Electrode	11 04 04 01	
2113	EasyLyte Cl- Electrode	11 04 01 03	
2106	EasyLyte Lithium Electrode	11 04 01 04	
2150	EasyLyte Ca++ Electrode	11 04 01 02	
2151	EasyLyte pH Electrode	11 70 31 02	
2152	EasyLyte Disposable Reference Electrode	11 04 04 01	
2109	EasyLyte Solutions Pack, 400mL	11 04 04 02	
2120	EasyLyte Solutions Pack, 800mL	11 04 04 02	
2112	EasyLyte Plus Solutions Pack, 400mL	11 04 04 02	
2121	EasyLyte Plus Solutions Pack, 800mL	11 04 04 02	
2115	EasyLyte Lithium Solutions Pack, 400mL	11 04 04 02	
2122	EasyLyte Lithium Solutions Pack, 800mL	11 04 04 02	
2114	EasyLyte Calcium Solutions Pack, 400mL	11 04 04 02	
2123	EasyLyte Calcium Solutions Pack, 800mL	11 04 04 02	
2026	EasyLyte Na/K/Cl/Li Solutions Pack, 800mL	11 04 04 02	
2028	EasyLyte Na/K/Cl/Li Solutions Pack, 400mL	11 04 04 02	
2124	EasyLyte Na/K/Cl/Ca/Li Solutions Pack, 800mL	11 04 04 02	

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Catalog No.	EasyLyte Analyzer and Accessories	EDMA Code	Class
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04	General IVD device, other than listed in IVDD Annex II and other than intended for self-testing
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04	
L2026	EasyLyte Solutions Pack, Na/K/Cl/Li, 800mL	11 04 04 02	
L2112	EasyLyte Solutions Pack, Na/K/Cl, 400mL	11 04 04 02	
L2121	EasyLyte Solutions Pack, Na/K/Cl, 800mL	11 04 04 02	
L2122	EasyLyte Solutions, Na/K/Li Pack, 800mL	11 04 04 02	
L2123	EasyLyte Solutions Pack, Na/K/Ca/pH, 800mL	11 04 04 02	

Declaration of CE conformity

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

Teugseweg 20
7418 AM Deventer
the Netherlands

herewith declares the following:

The reagents (see attached list) are labeled with the J.T. Baker label and have the CE mark on the label where applicable. The devices comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the conformity assessment procedure according to Annex III.
The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self registration.
This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking.

Deventer, the Netherlands.
22 November 2011

Dr. J. Mittendorf
QA & RA Manager

J.T.Baker product list for CE marked products

Prod.no.	Product	Pack size
Reagents for diluting and lysing		
3961	Diluid™ 100 Plus	20 liter
3954	Diluid 590	20 liter
3969	Diluid 610	20 liter
3430.9010	Diluid Abacus	10 liter
3430.9020	Diluid Abacus	20 liter
3996	Diluid AC 900	20 liter
3996.9010PC	Diluid AC 900	10 liter
3476.9020PC	Diluid APR	20 liter
3957	Diluid Azide free	20 liter
3958	Diluid Azide free	10 liter
3963.9010	Diluid III Diff	10 liter
3963	Diluid III Diff	20 liter
3974	Diluid III Diff Seaccontainer	20 liter
3459.9020	Diluid Erma	20 liter
3483.9020PC	Diluid NR	20 liter
3439.9020PC	Diluid Mindray	20 liter
3832.9020	Diluid Sheath 3200-4000	20 liter
3976	Diluid ST 1600/2000	20 liter
3496.9020PC	Diluid M5	20 liter
3495.9010PC	Sheath D	10 liter
3826	Sheath Fluid 3000/3500	20 liter
3826.5000	Sheath Fluid 3000/3500	5 liter
3827.5000PC	LeucoLyse	5 liter
3998	CN-free Lyse Diff AC 900	5 liter
3744	CyMet™ 1000 CN free	5 liter
3773.5000PC	CyMet 4500 CN free	5 liter
3824	CyMet 3000	10 liter
3823.1000	CyMet 3200 CN free	1 liter
3825	CyMet 3500 CN free	5 liter
3839.5000PC	CyMet 3500	5 liter
3975	CyMet 530+ CN free	10 liter
3971	CyMet 590 CN free	5 liter
3970	CyMet 610 CN free	10 liter
3977	CyMet 610 CN free	5 liter
3918.5000	CyMet 9000 CN free	5 liter
3431.1000	CyMet Abacus CN free	1 liter
3444.1000PE	CyMet Abacus EO	1 liter
3445.1000PE	CyMet Abacus Baso	1 liter
3477.0500PE	CyMet APR CN free	500 ml
3478.1000PE	CyMet APR EO	1 liter
3479.1000PE	CyMet APR Baso II	1 liter
3755	CyMet Automated	5 liter
3757	CyMet Automated	500 ml
3780	CyMet Automated CN Free	1 liter
3460.0500	CyMet Erma	500 ml
3841.1000PE	CyMet H12 CN Free	1 liter
3842.1000	EO Reagent Autocounter	1 liter
3853.1000	CyMet H20	1 liter
3968	CyMet III Diff	1 liter
3964	CyMet III Diff	5 liter
3972.1000	CyMet III Diff CN free	1 liter
3972.5000	CyMet III Diff CN free	5 liter
3740.0500	CyMet KX CN Free	500 ml
3852.1000	CyMet Micro	1 liter
3852.0500	CyMet Micro	500 ml
3857.1000	CyMet Micro CN free	1 liter
3857.0500	CyMet Micro CN free	500 ml
3863.1000	CyMet Micro CN free	1L micros
3440.0500PE	CyMet Mindray CN Free	500 ml
3441.0500PE	CyMet Mindray	500 ml
3480.5000PC	CyMet SF Baso	5L
3481.5000PC	CyMet SF Diff 1	5L
3482.0500PE	CyMet SF Diff 2	500 ml
3775.1000	CyMet ST 1600/2000	1 liter
3759.1000	CyMet ST 1600/2000 CN free	1 liter
3759.5000	CyMet ST 1600/2000 CN free	5 liter
3788	CyMet STX/STL	1 liter
3919	CyMet STX/STL	5 liter
3484.1000PE	CyMet NR III	1 liter
3486.1000PE	CyMet NR III, CN Free	1 liter
3485.1000PE	CyMet NR V	1 liter
3497.0500PE	CyMet MH CN Free	500 ml
3489.1000PE	CyMet MBA	1 liter
3487.1000PE	CyMet MD(I)	1 liter
3488.0500PE	CyMet MD(II)	500 ml
3077	LyzerGlobin™	500 ml
3769	LyzerGlobin	6 x 15 ml
3771	LyzerGlobin PCE	6 x 15 ml
3770	LyzerGlobin II	10 x 10 ml
3850	LyzerGlobin CN free	6 x 15 ml
Cleaners		
3766.0500	DetectoTerge	500 ml
3763	DetectoTerge	5 liter
3766	DetectoTerge	1 liter
3900	ProClean™	5 liter
3768.1000	ProClean	1L micros
3867.1000PE	ProClean Extra	1L micros
3862.1000	ProClean Extra	1 liter
3862.5000	ProClean Extra	5 liter
3901	ProClean Plus	100 ml
3902.0100PE	ProClean CD	100 ml
3432.5000	ProClean Abacus	5 liter
3946	Blanking Solution Hgb	20 liter
3947	Blanking Solution 1600/2000	20 liter
3917	Hypochlorite 0.5%	1liter
3917.5000	Hypochlorite 0.5%	5 liter
3936.1000	Hypochlorite 5%	1liter
3442.5000PE	Rinse Mindray	5 liter
3915	Rinsing Solution Serono 9000	20 liter
3941.1000PE	HypoChlorite NR	1 liter
3941.5000PC	HypoChlorite NR	5 liter
3498.1000PE	ProClean MX5	1 liter
Reagents for 5-part WBC diff. on STKS and MaxM.		
3938	RBCLyse™	1 liter
3938G.1000PE	RBCLyse G	1 liter
3939	WBCStabilise™	500 ml
3492.0090	RetiCount MH	6 x 15 ml
3493.0500PE	RetiClear MHG	500 ml
3493.1000PE	RetiClear MHG	1 liter
3494.0200PE	RetiCount G	200 ml
3774	Reticount™	30 ml
3777	Reticount CD	15 x 3.5 ml

Hematology Controls		
3721/3722/3723	8 PMC Low/Normal/High	8 ml
3724/3725/3726	8 PMC Low/Normal/High	2.5 ml
3633/3634/3635	8 PMC Low/Normal/High ext	2.5 ml
3701/3702/3703	8 PMC Low/Normal/High	4.5 ml
3922/3923/3924	8 PMC L/N/H Swelab	4.5 ml
3746	8 PMC 1 x L,1 x N,1 x H	3 x 2.5 ml
3747	8 PMC 4 x Normal	4 x 2.5 ml
3748	8 PMC 4 x Normal	4 x 8 ml
3749	8 PMC 4 x Low	4 x 2.5 ml
3751	8 PMC 1x L, 4 x N, 1x H	6 x 2.5 ml
3734/3735/3736	3-Diff Control L/N/H	2.5 ml
3630/3631/3632	3-Diff Control L/N/H ext	2.5 ml
3820/3821/3822	3-Diff Control L/N/H	4.5 ml
3752	3-Diff Control 4 x Low	4 x 2.5 ml
3753	3-Diff Control 4 x Norm	4 x 2.5 ml
3754	3-Diff Control 4 x High	4 x 2.5 ml
3782/3783/3784	CA-Diff Control L/N/H	4.5 ml
3607/3608/3609	CA-Diff Control L/N/H	2.5 ml
3610/3611/3612	DIA Diff 5 Control L/N/H	4.5 ml
3731/3732/3733	XE-Diff Control L/N/H	4.5 ml
3693/3694/3695	SF-Diff Control L/N/H	4.5 ml
3613/3614/3615	BC Diff 5 Control L/N/H	4.5 ml

3684/3685/3686	ADV-Diff Control L/N/H	3.5 ml
3690/3691/3692	ADV Retic 1/2/3	4.0 ml
3828/3829/3830	CD-Diff Control	3.0 ml
3838	CD-Diff Control 2x L,N,H	6 x 3.0 ml
3687/3688	CD 4K Retic 1/2	3.0 ml
3892/3893/3894	AC-Diff Control	2.5 ml
3896/3897/3898	K-Diff Control	2.5 ml
3696/3697	WBC reduced Plt Control L/H	3.0 ml
3698/3699	WBC reduced RBC Control L/H	3.0 ml
Laser controls for Coulter MaxM, GenS and STKS		
3681/3682/3683	5D Control Low /N /H	5.0 ml
Calibration Set for Cell Analysers.		
3940	Cal Set 1	2 x 2.5 ml
3720	Platelet Control Ext. value	5 x 3 ml
Phosphate Buffered Saline.		
3059	PBS, diluting fluid for bloodgrouping	20 liter
3059.9010PC	PBS, diluting fluid for bloodgrouping	10 liter

Number	Product	Content
	Stains and Dyes	
3554.1000PE	Papanicolaou Solution 2A	1 liter
3554.2500PE	Papanicolaou Solution 2A	2.5 liter
3554.9200PE	Papanicolaou Solution 2A	200 liter
3555.1000PE	Papanicolaou Solution 2B	1 liter
3555.2500PE	Papanicolaou Solution 2B	2.5 liter
3556.1000PE	Papanicolaou Solution 3B	1 liter
3556.2500PE	Papanicolaou Solution 3B	2.5 liter
3556.9200PE	Papanicolaou Solution 3B	200 liter
3800.1000PE	Eosine-Y Alcoholic	1 liter
3800.2500PE	Eosine-Y Alcoholic	2.5liter
3801.1000PE	Eosin Y 0.5% Aqueous	1 liter
3801.2500PE	Eosin Y 0.5% Aqueous	2.5liter
3871.1000	Eosine Solution 0.2% ready to use	1 liter
3871.2500	Eosine Solution 0.2% ready to use	2.5 liter
3856.0100	Giemsa	0.1 liter
3856.0500	Giemsa	0.5 liter
3856.1000	Giemsa	1 liter
3856.2500	Giemsa	2.5 liter
3870.1000	Hematoxyline er (Mayer)	1 liter
3870.2500	Hematoxyline er (Mayer)	2.5 liter
3873.1000	Hematoxyline (Harris, Gill II)	1 liter
3873.2500	Hematoxyline (Harris, Gill II)	2.5 liter
3879.1000	Leishman	1 liter
3855.0500	May Grünwald	0.5 liter
3855.1000	May Grünwald	1 liter
3855.2500	May Grünwald	2.5 liter

3864.1000	Papanicolaou 2A OG6	1 liter
3864.2500	Papanicolaou 2A OG6	2.5 liter
3865.1000	Papanicolaou 2B Orange II	1 liter
3865.2500	Papanicolaou 2B Orange II	2,5 liter
3866.1000	Papanicolaou 3B EA 50	1 liter
3866.2500	Papanicolaou 3B EA 50	2,5 liter
3876.1000	Shorr	1 liter
3878.1000	Wright	1 liter
	Clearing agent	
3905.2500PE	UltraClear	2.5 liter
3905.5000PE	UltraClear	5 liter
3905.9010PE	UltraClear	10 liter
3905.9200	UltraClear	200 liter
	Mounting media	
3921.0500	UltraKitt	500 ml
3921.0600	UltraKitt	6 x 100 ml
	Fixatives	
3933.1000	10% v/v Buffered Formaldehyde	1 liter
3933.5000PC	10% v/v Buffered Formaldehyde	5 liter
3933.9010 (PE)	10% v/v Buffered Formaldehyde	10 liter (PE)
3933.9020 (PE)	10% v/v Buffered Formaldehyde	20 liter (PE)
3869.1200	Cervix Fixative	12 x 125 ml
3880.1000	Bouin's Fixative	1 liter
3058.9010	Immuno PBS 20x concentrated	10 liter

22 November 2011

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Conformity Declarations

Archem Diagnostics Systems

Declares in our own responsibility conformity of the products listed below according to the essential requirements in other IVD products the Directive 98 / 79 / EC on *in vitro* diagnostic medical devices (IVD Directive)

CE

archem
SAĞLIK SAN. VE TİC. ANONİM ŞTİ.
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archem DIAGNOSTICS

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ZA17B4-R1	D-Dimer Reagent
ZA17B4-R2	D-Dimer Reagent
ZA17B20-R1	D-Dimer Reagent
ZA17B20-R2	D-Dimer Reagent
PR21B1-R1	Procalcitonin Reagent
PR21B1-R2	Procalcitonin Reagent
5110M	PlasmaDiluent III
5121M	StromaLyse III
5131M	CleanAr
5120R	StromaLyse
9020R	CleanAr
5310C	PlasmaDiluent C
5321C	StromaLyse C
5330C	CleanAr
5340C	Concentrated Cleanacer
5910MN	PlasmaDiluent III
5911MN	PlasmaDiluent III
5950MN	DS Dilüent
5920MN	StromaLyse
5921MN	StromaLyse MN
5930MN	CleanAr
5931MN	CleanAr
5940MN	Concentrated Cleanacer
5941MN	PROBE CleanAr
5810AB	PlasmaDiluent
5811AB	PlasmaDiluent
5820AB	StromaLyse ABB
5821AB	StromaLyse ABB
5830AB	CleanAr
5831AB	CleanAr
5840AB	Concentrated Cleanacer
5611SW	PlasmaDiluent
5621SW	StromaLyse SW
5631SW	CleanAr
6410DN	PlasmaDiluent
6411DN	PlasmaDiluent
6420DN	StromaLyse DN
6421DN	StromaLyse DN
6430DN	CleanAr
6431DN	CleanAr
6440DN	Concentrated Cleanacer

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5410A	PlasmaDiluent A
5411A	PlasmaDiluent A
5420A	StromaLyse A
5421A	StromaLyse A
5430A	CleanAr
5431A	CleanAr
5440A	Concentrated Cleanacer
7310ER	PlasmaDiluent
7311ER	PlasmaDiluent
7320ER	StromaLyse E
7321ER	StromaLyse E
7322ER	StromaLyse E
7330ER	CleanAr
7340ER	Concentrated Cleanacer
6011MD	PlasmaDiluent III
6020MD	StromaLyse MD
6021MD	StromaLyse MD
6031MD	Cleaner MD Sample
6030MD	CleanAr
6040MD	Concentrated Cleanacer
6211HY	PlasmaDiluent
6220HY	StromaLyse HY
6221HY	StromaLyse HY
6231HY	CleanAr HY
6240HY	Concentrated Cleanacer
5211R	PlasmaDiluent
5220R	StromaLyse HY
5221R	StromaLyse HY
6510ML	PlasmaDiluent
6511ML	PlasmaDiluent
6520ML	StromaLyse DIFF
6521ML	M REF CONC
8111AR	PlasmaDiluent
8110AR	PlasmaDiluent
8112AR	PlasmaDiluent C
8120A	StromaLyse
8121A	StromaLyse
8130A	CleanAr
8131A	CleanAr
8132A	CleanAr
8140A	Concentrated Cleanacer

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6710S	PlasmaDiluent
6711S	PlasmaDiluent
6720S	StromaLyse E
6721S	StromaLyse E
6730S	CleanAr
6740S	Concentrated Cleanacer
5111M	PlasmaDiluent III
5120M	StromaLyse III
5130M	CleanAr
5125B	StromaLyse B
5128B	StromaLyse EOS
5140M	Concentrated Cleanacer
7110N	PlasmaDiluent III
7111N	PlasmaDiluent III
7210N	StromaLyse
7211N	StromaLyse
7220N	CleanAr
7230N	Concentrated Cleanacer
7010P	PlasmaDiluent
7011P	PlasmaDiluent
7020P	StromaLyse
7021P	StromaLyse
7030P	CleanAr
7031P	CleanAr
7040P	Concentrated Cleanacer
5311C	PlasmaDiluent C
5320C	StromaLyse C
5325C	StromaLyse ALFA
5231R	CleanAr
5240R	Concentrated Cleanacer
7310S	PlasmaDiluent
7320S	StromaLyse
7321S	StromaLyse
7330S	CleanAr HY
7340S	Concentrated Cleanacer
8210DW	PlasmaDiluent
8220DW	StromaLyse
8221DW	StromaLyse
8230DW	CleanAr
8240DW	Concentrated Cleanacer
8310HX	PlasmaDiluent

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Appendix to

Conformity Declarations

Archem Diagnostic Systems

Conformity also declared with all aplicable harmonized standards, especially the following:

EN ISO 13485: Medical devices — Quality management systems — Requirements for regulatory purpose.

EN ISO 14971: Medical devices — Application of risk management to medical devices.

EN ISO 17511: In vitro diagnostic medical devices — Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials.

EN ISO 18113-1: In vitro diagnostic medical devices —Information supplied by themanufacturer (labelling) — Part 1: Terms, definitions and general requirements.

EN ISO 18113-2: In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for Professional use.

Other standards applied:
EN ISO 9001: Quality management systems

Note: Standards are used in this issue that is valid at date of issue of this conformity declaration.

Commercial Director
Erkan Uca
06.10.2022

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

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

TÜV SÜD Product Service

Certificate

No. Q5 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®

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.:	SX 1614112-1
Certificate Holder:	KABE-Labortechnik GmbH Jägerhofstr. 17 51588 Nümbrecht Germany
Scope:	Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices: - cannulas for blood collection, - winged cannulas for blood collection and - capillaries for micro blood collection (KABE MBU capillaries).

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.:	1160508-40
Effective date:	2024-10-16
Expiry date:	2027-10-15
Issue date:	2024-09-24

Replaces certificate SX 1614112-1 issued 2021-10-25.

This certificate can be validated on https://www.certipedia.com

Dipl.-Ing. (FH) Daniele Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜVRheinland® Precisely Right.

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 1614112-1

Certificate Holder: KABE-Labortechnik GmbH
Jägerhofstr. 17
51588 Nümbrecht
Germany

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o KABE-Labortechnik GmbH Jägerhofstr. 17 51588 Nümbrecht Germany	Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices
/02	c/o KABE-Labortechnik GmbH Werner-von-Siemens-Str. 1 51674 Wiehl Germany	Warehouse and shipping

This certificate can be validated on https://www.certipedia.com

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

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