Digitally signed by Ceaicovschi Tudor
Date: 2024.01.26 14:48:37 EET
Reason: MoldSign Signature
Location: Moldova

nqa global assurance

Certificate of Registration

This is to certify that the Quality Management System of:

Avantor Fluid Handling B.V.

Maidstone 50
5026 SK Tilburg
The Netherlands

applicable to:

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

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

ISO 9001:2015

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

For and on behalf of NQA, USA

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

Avantor Performance Materials Poland Spółka Akcyjna
Sowińskiego 11
44-101 Gliwice
Tel. 48 32 2392 000

Declaration of conformity

Avantor Performance Materials Poland S.A. who is an established manufacturer of reagents and products for diagnostic in vitro located at:

Sowińskiego 11 Street
44-101, Gliwice
Poland

Herewith declares the following:
Reagents mentioned in attached list are labeled with J.T.Baker label, comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the requirements of ISO 13485 Standard.
This declaration is the basic for CE marking of the In Vitro Diagnostic Medical Devices.
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

Gliwice, Poland

January 25, 2019

Anna Szuba
Quality Director

NIP 631-010-13-07
Numer w KRS: 0000010108
Sąd rejestrowy: Sąd Rejonowy w Gliwicach
X Wydział Gospodarczy KRS
Kapitał zakładowy 2 360 793,00 zł
Regon: 271563380

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Diluents		
Diluid™ 100 Plus	3961	20 L
Diluid™ 22	2990.9010PC	10 L
Diluid™ 610	3969	20 L
	3969-00	20 L
Diluid™ Abacus	3430,9020	20 L
	3430,9010	10 L
	3430-00	20 L
Diluid™ AC 900	3996	20 L
Diluid™ APR	3476.9020PC	20 L
Diluid™ Azide free	3957	20 L
Diluid™ III Diff	3963	20 L
	3963.9010	10 L
	3963-00	20 L
Diluid™ Erma	3459,9020	20 L
	3459-00	20 L
Diluid™ Mindray	3439.9020PC	20 L
	3439-00	20 L
Diluid™ NR	3483.9020PC	20 L
	3483-00	20 L
Diluid™ Ruby	2987.9020PC	20 L
Diluid™/Sheath 3200-4000	3832,9020	20 L
Diluid™ ST1600/2000	3976	20 L
Sheath D	3495.9010PC	10 L
Sheath Fluid 3000/3500	3471.9020PC	20 L
Lyses		
CN-free Lyse Diff AC 900	3998	5 L
CyMet™ 22 CN Free	2986.0500PE	500 ml
CyMet™ 3000	3469.9010PC	10 L
CyMet™ 3200 CN free	3823,1000	1 L
CyMet™ 3500	3839.5000PC	5 L
CyMet™ 3500 CN free	3825	5 L
CyMet™ 610 CN free	3970	10 L
	3970-00	10 L
	3977	5 L
CyMet™ Abacus CN free	3431,1000	1 L
	3431-00	1 L
CyMet™ APR Baso II	3479.1000PE	1 L
CyMet™ APR CN free	3417.0500PE	500 ml
CyMet™ APR EO	3478.1000PE	1 L
CyMet™ ASA	2950.2500PE	2.5 L
CyMet™ ASB	2951.0500PE	500 ml
CyMet™ AS CN free	2952.9010PC	10 L
CyMet™ BS3 CN free	2982.0500PE	500 ml
CyMet™ III Diff	3968	1 L
	3968-00	500 ml
CyMet™ III Diff CN free	3511,1000	1 L
	3511-00	5 L
CyMet™ Erma	3416-00	500 ml
	3416,0500	500 ml
CyMet™ H20	3853,1000	1 L
CyMet™ KX CN Free	3425-00	500 ml
	3425,0500	500 ml
CyMet™ Micro	3852,1000	1 L
CyMet™ Micro CN free	3863,1000	1 L micros
	3863-00	1 L micros
CyMet™ Mindray	3441-00	500 ml
CyMet™ Mindray CN Free	3440.0500PE	500 ml

J.T.Baker product list for CE marked products

Product	Product number	Pack size
CyMet™ NR III	3484.1000PE	1 L
CyMet™ NR III CN Free	3486-00	1 L
	3486.1000PE	1 L
CyMet™ NR V	3485.1000PE	1 L
CyMet™ Ruby CN Free	2988.5000PC	5 L
CyMet™ ST 1600/2000 CN free	3759.5000	5 L
LeucoLyse	3475.5000PC	5 L
LeucoLyse Ruby	2989.5000PC	5 L
Cleaners		
Blanking Solution 1600/2000	3947	20 L
DetectoTerge™	3763	5 L
	3766	1 L
DetectoTerge™ BS	2970.0900PE	900 ml
ProClean™	3900	5 L
	3900-00	5 L
	3768,1000	1 L micros
ProClean™ Abacus	3432,5000	5 L
	3432.1000PE	1 L
ProClean™ CD	3902.0100PE	100 ml
ProClean™ Extra	3862,5000	5 L
	3862.9020PC	20 L
	3862-00	5 L
	3867-00	1 L micros
	3867.1000PE	1 L micros
ProClean™ Plus	3901	100 ml
Rinse Mindray	3442.5000PE	5 L
Hematology Controls		
8-Parameter Control L/N/H	3427/3428/3429	2.5 ml
	3463/3464/3465	2.5 ml
8-Parameter Control 4xN	3747	4 x 2.5 ml
8-Parameter Control 1xL+4xN+1xH	3751	6 x 2.5 ml
8-Parameter Control extended L/N/H	3633/3634/3635	2.5 ml
3-Diff Control L/N/H	3433/3434/3435	2.5 ml
	3502/3503/3504	4.5 ml
3-Diff Control extented L/N/H	3421/3422/3423	2.5 ml
CD-Diff Control L/N/H	3452/3453/3454	3.0 ml
CD-Diff Control 2xL+2xN+2xH	3838	6 x 3.0 ml
K-Diff Control L/N/H	3455/3456/3457	2.5 ml
Platelet Control- Extended value	3424	5 x 3.0 ml
WBC Reduced RBC L/H	3698/3699	3.0 ml
XE-Diff Control L/N/H	3731/3732/3733	4.5 ml
Fixatives		
Cervix Spray Fixative	3869,1200	12 x 125 ml
10% v/v Buffered Formaldehyde (4% w/v)	3933,1000	1 L
	3933.5000PC	5 L
	3933,9010	10 L
	3933,9020	20 L
	3933.1000MB	1000 L
	3933.9020PE	20 L
	3933.9010JL	10 L
	3933.9020JL	20 L
Clearing agents		
UltraClear™	3905.2500PE	2.5 L
	3905.5000PE	5 L
	3905.9010PE	10 L

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Stains and Dyes		
Eosin-Y Alcoholic	3800.1000PE	1 L
	3800.2500PE	2.5 L
Giemsa	3856,1000	1 L
	3856,2500	2.5 L
	3856.9180ST	180 L
Hematoxylin er (Mayer)	3870,1000	1 L
	3870,2500	2.5 L
Hematoxylin Modified (Harris, Gill II)	3873,1000	1 L
	3873,2500	2.5 L
May-Grünwald	3855,1000	1 L
	3855,2500	2.5 L
Papanicolaou 2A	3554.1000PE	1 L
	3554.2500PE	2.5 L
Papanicolaou 2B	3555.1000PE	1 L
	3555,2500PE	2,5 L
Papanicolaou 3B	3556,1000PE	1 L
	3556.2500PE	2.5 L
Mounting media		
UltraKitt™	3921,0500	500 ml
	3921,0600	6 x 100 ml
	3921,9025ST	25 L
Mounting medium High	3882,0500	500 ml
Mounting medium Low	3883,0500	500 ml
PBS		
PBS	3059	20 L
	3059.9010PC	10 L

Archem Sağlık San. ve Tic. A.Ş.
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Fax: +90 (212) 629 98 89
info@archem.com.tr
www.archem.com.tr

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.
Mahmutbey Mah. Halkalı Cad. No:124/42
Bağcılar/İST. Tel:444 08 92 Fax:0212 629 98 89
Güneşli V.D.:0730790980

archem DIAGNOSTICS

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Fax: +90 (212) 629 98 89
info@archem.com.tr
www.archem.com.tr

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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www.archem.com.tr

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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Mahmutbey Mah. Halkalı Cad. No:124/42
Bağcılar/İST. Tel: 444 08 92 Fax:0212 629 98 89
Gümrük V.D.:0730790980

Archem Diagnostics Industry Inc.
Mahmutbey Mah. Halkalı Cad. No:124 Bağcılar, ISTANBUL TURKEY
Tlf: + 90 212 444 08 92 Fax: +90 212 629 98 89 info@archem.com.tr www.archem.com.tr

Certificate JP06/040143

The management system of

ERMA INC.

3-4-8 Kiuri, Yoshikawa-shi, Saitama-ken, 342-0045 Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

1. Manufacture and service of blood cell counters, spectrophotometric analyzers for IVD use and bilirubin analyzers
2. Distribution of in-vitro diagnostic products for hemoglobin measurement

This certificate is valid from 16 November 2021 until 16 November 2024 and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 10. Certified since 16 November 2006

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 13485 2016 0421

Certificate of Completion

This is to certify

Mr. Alexei Legun

Has successfully completed

The technical maintenance training course

On

Fully Automatic Blood Cell Counter

PCE-210

Particle(Blood Cell)Counter

PCE-170/PCE-170N

Hemoglobin meter

Hb-20N

March 24, 2005

Hiroshi Shimosaka
President
ERMA INC.

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, 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
Latest Revision Date: 2022-04-12

Effective Date: 2021-10-13
Expiry Date: 2024-10-12

...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, 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: 2021-10-13

Latest Revision Date: 2022-04-12

Expiry Date: 2024-10-12

By Royal Charter

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

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-06-01
Latest Revision Date: 2022-06-22

Effective Date: 2021-10-13
Expiry Date: 2024-10-12

...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.
Abbott Japan LLC 278 Matsuhidai Matsudo-shi Chiba 270-2214 Japan	Design and Development of in vitro diagnostics products including test kits and reagents.

Original Registration Date: 2021-06-01

Effective Date: 2021-10-13

Latest Revision Date: 2022-06-22

Expiry Date: 2024-10-12

Abbott

Declaration of Conformity

Certificate Identification: SC-09H46

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

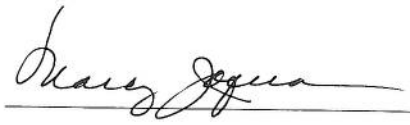
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

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

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. 00

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

Certification Mark:

TÜV SÜD
DIN EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate:

Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Clinical Chemistry and Hematology (Co-Oximeter) Medical Devices including Near Patient / Point of Care Analyzers, Calibrators, Controls, Reagents, Sensors, Kits used in the Detection of Blood Analytes, Electrolytes, pH, Metabolites; Self Testing and Near Patient / Point of Care In-Vitro Diagnostic Devices for the Management of Diabetes Blood Glucose, Ketone, Cholesterol and Uric Acid, including Meters, Test Strips and Controls; Self Testing In-Vitro Diagnostic Medical Devices for the Determination of the percent Hemoglobin A1c (HbA1c), Total Cholesterol, High Density Lipoprotein (HDL) Cholesterol and Triglycerides in Whole Blood, and Albumin and Creatinine in Urine including Analyzers, Test Cartridges and Controls; Contract Manufacturing of Electronic Medical Devices; Contract Manufacturing of Disposable Medical Devices; 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 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 020747 0242 Rev. 00

Report No.: 72166286

Valid from: 2021-10-29
Valid until: 2024-10-28

Date, 2021-10-29

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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. 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):

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

Production of Near Patient / Point of Care, and Self-Testing Meters for the Management of Diabetes Blood Glucose, Ketone, Cholesterol and Uric Acid.

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

Production of Near Patient / Point of Care, and Self-Testing Test Strips for the Management of Diabetes Blood Glucose, Ketone, Cholesterol and Uric Acid.
Distribution of Near Patient / Point of Care, and Self-Testing Test Strips, Meters and Controls. Distribution of Lancets.

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

Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Clinical Chemistry and Hematology (Co-Oximeter) Medical Devices including Near Patient / Point of Care Analyzers, Calibrators, Controls, Reagents, Sensors, Kits used in the Detection of Blood Analytes, Electrolytes, pH, Metabolites; Self Testing and Near Patient / Point of Care In-Vitro Diagnostic Devices for the Management of Diabetes Blood Glucose, Ketone, Cholesterol and Uric Acid, including Meters, Test Strips and Controls; Self Testing In-Vitro Diagnostic Medical Devices for the Determination of the percent Hemoglobin A1c (HbA1c), Total Cholesterol, High Density Lipoprotein (HDL) Cholesterol and Triglycerides in Whole Blood, and Albumin and Creatinine in Urine including Analyzers, Test Cartridges and Controls; Contract Manufacturing of Electronic Medical Devices; Contract Manufacturing of Disposable Medical Devices

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

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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

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 07 декабря 2015 года № ФСР 2011/11306

На медицинское изделие
Краситель Азур-Эозин по Романовскому (МиниМед-Р)
по ТУ 9398-003-29508133-2011

Настоящее регистрационное удостоверение выдано
Общество с ограниченной ответственностью "МиниМед"
(ООО "МиниМед"), Россия,
241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Производитель
Общество с ограниченной ответственностью "МиниМед"
(ООО "МиниМед"), Россия,
241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А

Место производства медицинского изделия
241520, Брянская область. Брянский район, с. Супонево, пер. Комсомольский, д. 7, корп. 2-а

Номер регистрационного досье **№ РД-9275/51846 от 18.11.2015**

Вид медицинского изделия **232730**

Класс потенциального риска применения медицинского изделия **3**

Код Общероссийского классификатора продукции для медицинского изделия **93 9816**

приказом Росздравнадзора от 07 декабря 2015 года № 9111
допущено к обращению на территории Российской Федерации.

Руководитель Федеральной службы
по надзору в сфере здравоохранения **М.А. Мурашко**

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