

# EC Certificate

**Full Quality Assurance System  
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,  
Annex IV excluding (4, 6)**

Registration No.: HL 1038121-1

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

Products: Products for self-testing  
- Single and multi-parameter disposable test strips for urine analysis  
- Indicator test strips and papers for measurement of pH in urine

Replaces Certificate, Registration No.: HL 60119814 0001

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16



Dipl.-Ing. Sven Hoffmann  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.



TÜVRheinland®

# EC Certificate

**Full Quality Assurance System  
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,  
Annex IV excluding (4, 6)**

Registration No.: HL 1038121-1

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

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	MACHEREY-NAGEL GmbH & Co. KG Valenciener Str. 11 52355 Düren Germany	Design and development, manufacture and quality control
/02	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16



*S. Hoffmann*  
Dipl.-Ing. Sven Hoffmann  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.



*Certificate of Completion*

*this is to certify*

***Mr. Alexei Legun***

*has successfully completed*


*The technical maintenance training course*

*On*

*Urine Analysis*

*URYXXON 200;  
URYXXON RELAX;  
URYXXON 500;*

Mars, 2006



*President*

MACHEREY-NAGEL GMBH & CO.KG

# Certificate

Standard **ISO 9001:2015**

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

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

including the locations according to annex

Scope: Design, development, production and distribution of products  
for filtration, rapid tests, water analysis, service and administration

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

Validity: The certificate is valid from 2020-05-29 until 2023-05-28.

2022-05-03 (Change)



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Annex to certificate

Standard **ISO 9001:2015**

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

No.	Location	Scope
/01	c/o MACHEREY-NAGEL GmbH & Co. KG Valenciener Str. 11 52355 Düren Germany	Design, development, production and distribution of products for filtration, rapid tests, water analysis, service and administration
/02	c/o MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design, development and production of products for chromatography and bioanalysis
/03	c/o MACHEREY-NAGEL GmbH & Co. KG Papiermühle 50 52349 Düren Germany	Waste disposal
/04	c/o MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Storage
/05	c/o MACHEREY-NAGEL GmbH & Co. KG Monschauer Str. 64 52355 Düren Germany	Production

2022-05-03

  
TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Certificate



## Quality Management System EN ISO 13485:2016

Registration No.: SX 1038121-1

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

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

(see attachment for sites included)

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

Report No.: 1094054 -20  
Effective date: 2020-05-29  
Expiry date: 2023-05-28  
Issue date: 2022-02-16



Dipl.-Ing. S. Hoffmann  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

# Certificate

Quality Management System  
EN ISO 13485:2016

Registration No.: SX 1038121-1

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

The scope of certification also covers the following:

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

Report No.: 1094054 -20  
Effective date: 2020-05-29  
Expiry date: 2023-05-28  
Issue date: 2022-02-16

# Certificate

## Specialized Waste Management Company

Certificate Registration No.: 01 400 0114 (Certificate for Decoration)

On 2022-03-11 TÜV Rheinland Cert GmbH carried out a voluntary inspection on the premises of

**MACHEREY-NAGEL  
GmbH & Co. KG  
Valenciennner Straße 11  
D- 52355 Düren**



as part of a repeat audit with regard to the criteria contained in the Ordinance on Specialized Waste Management Companies (EfbV) on the basis of Art. 56 and 57 KrWG.

### This Certificate is valid for

#### Site

**Papiermühle 50 ♦ D- 52349 Düren**

(Waste producer number: **E35828749**, waste management number: **E35837000**)

**and covers the storage, treatment and disposal of waste Code no. 16 05 06\*, 16 05 07\* and 16 05 08\* as stated in annex 1 of the official certificate according to annex 3 of EfbV.**

Evidence was provided in Audit Report No. 37189536 that the above conditions have been met.

According to Art. 22 EfbV this Certificate **is valid until 2023-08-31**. The next audit (at least one audit per year as specified in Art. 22 EfbV) **will be conducted until 2023-02-28**. **This Certificate is valid only in connection with the official certificate dated from 2022-07-13 according to annex 3 of EfbV.**

Cologne, 2022-07-13

TÜV Rheinland Cert GmbH  
EfbV- Certification Body  
Christoph Schmieder

EfbV- Expert  
Thomas Nitsche





**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**



**Date:** Jul/29/2020

**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



Product Service

# Certificate

No. Q5 020747 0242 Rev. 00

**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 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](http://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

# 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

**NOVA**<sup>®</sup>  
*biomedical*

**CERTIFICATE OF COMPLETION**

*This is to certify that*

*Sergiu Sorocovici*

*has successfully completed Stat Profile Prime Plus Service and Application  
Training.*

**April 10-11, 2023**

**Date of Training**



**Huseyin Dibekkaya**

**Support Training Program Facilitator**

**International Regional Support Manager**

**Chişinău / Moldova**

**Location of Training**

**PRIME PLUS / VET SHELF-LIFE & WARRANTY INFORMATION**

REV: 07/2021

**Stat Profile® Prime Plus and Stat Profile Prime Plus VET**



DESCRIPTION		WARRANTY	SHELF LIFE
<b>Sensors Cards</b>			
57820	Prime-Plus Sensor Card: w/ COOx (Standard)	14 Days/200 Samples*	12 Mos
57822	Prime-Plus Sensor Card: w/ COOx (High Volume)	14 Days/400 Samples*	12 Mos
58642	Prime-Plus Sensor Card: NO COOx (Standard)	14 Days/200 Samples*	12 Mos
58643	Prime-Plus Sensor Card: NO COOx (High Volume)	14 Days/400 Samples*	12 Mos
57821	Prime-Plus: Renal Micro Sensor Card	7 Days/200 Samples*	12 Mos
58577	Prime-Plus VET- Sensor Card: w/ COOx (High Volume)	14 Days/400 Samples*	12 Mos
58578	Prime-Plus VET- Sensor Card: NO COOx (High Volume)	14 Days/400 Samples*	12 Mos
58581	Prime-Plus VET- Renal Micro Sensor Card	7 Days/200 Samples*	12 Mos
58379	Prime-Plus Sensor Card- BLANK RENAL Sensor Card: (Clinical & VET)	Free of Defects	n/a
57823	Reference Sensor- Prime-Plus (w/ W/R Pump Tubing) (CLINICAL)	Free of Defects	18 Mos
59345	Reference Sensor- Prime-Plus (w/ W/R Pump Tubing) (VET)	Free of Defects	18 Mos
<b>Calibrators</b>			
57825	Stat Profile Prime Plus® Calibrator Cartridge 100 Sample	100 Samples or 35 Days	18 Mos
57826	Stat Profile Prime Plus® Calibrator Cartridge 200 Sample	200 Samples or 35 Days	18 Mos
57827	Stat Profile Prime Plus® Calibrator Cartridge 300 Sample	300 Samples or 35 Days	18 Mos
57828	Stat Profile Prime Plus® Calibrator Cartridge 400 Sample	400 Samples or 35 Days	18 Mos
57829	Stat Profile Prime Plus® Calibrator Cartridge 500 Sample	500 Samples or 35 Days	18 Mos
57831	Stat Profile Prime Plus® Calibrator Cartridge 100 Sample with Creat / BUN	100 Samples or 21 Days	18 Mos
57832	Stat Profile Prime Plus® Calibrator Cartridge 200 Sample with Creat / BUN	200 Samples or 21 Days	18 Mos
57833	Stat Profile Prime Plus® Calibrator Cartridge 300 Sample with Creat / BUN	300 Samples or 21 Days	18 Mos
57834	Stat Profile Prime Plus® Calibrator Cartridge 400 Sample with Creat / BUN	400 Samples or 21 Days	18 Mos
57835	Stat Profile Prime Plus® Calibrator Cartridge 500 Sample with Creat / BUN	500 Samples or 21 Days	18 Mos
58395	Stat Profile Prime Plus® VET Calibrator Cartridge 200 Sample	200 Samples or 35 Days	18 Mos
58396	Stat Profile Prime Plus® VET Calibrator Cartridge 500 Sample	500 Samples or 35 Days	18 Mos
58405	Stat Profile Prime Plus® VET Calibrator Cartridge 200 Sample with Creat / BUN	200 Samples or 21 Days	18 Mos
58404	Stat Profile Prime Plus® VET Calibrator Cartridge 500 Sample with Creat / BUN	500 Samples or 21 Days	18 Mos
<b>AQC Packs</b>			
57838	Stat Profile Prime Plus® Auto QC Cartridge 160 Sample	160 Samples or 32 Days	18 Mos
57839	Stat Profile Prime Plus® Auto QC Cartridge 320 Sample	320 Samples or 32 Days	18 Mos
57840	Stat Profile Prime Plus® Auto QC Cartridge 480 Sample	480 Samples or 32 Days	18 Mos
57841	Stat Profile Prime Plus® Auto QC Cartridge 105 Sample with Creat / BUN	105 Samples or 21 Days	18 Mos
57842	Stat Profile Prime Plus® Auto QC Cartridge 210 Sample with Creat / BUN	210 Samples or 21 Days	18 Mos
57843	Stat Profile Prime Plus® Auto QC Cartridge 315 Sample with Creat / BUN	315 Samples or 21 Days	18 Mos
58406	Stat Profile Prime Plus® VET Auto QC Cartridge 160 Sample	160 Samples or 32 Days	18 Mos
58407	Stat Profile Prime Plus® VET Auto QC Cartridge 480 Sample	480 Samples or 32 Days	18 Mos
58408	Stat Profile Prime Plus® VET Auto QC Cartridge 105 Sample with Creat / BUN	105 Samples or 21 Days	18 Mos
58409	Stat Profile Prime Plus® VET Auto QC Cartridge 315 Sample with Creat / BUN	315 Samples or 21 Days	18 Mos
57844	Stat Profile Prime Plus® Ampuled Controls BG, COOX Levels 1, 2, 3	Free of Defects	12 Mos
57845	Stat Profile Prime Plus® Ampuled Controls Chemistry Levels 4,5	Free of Defects	12 Mos

57812	Stat Profile Prime Plus® VET Ampuled Controls BG, COOX Levels 1, 2, 3	Free of Defects	12 Mos
57813	Stat Profile Prime Plus® VET Ampuled Controls Chemistry Levels 4,5	Free of Defects	12 Mos

**Miscellaneous:**

52669	Luer Station Safety Port (5/pack) (Prime/Prime-Plus)	Free of Defects
52582	Probe/S-Line Assy : Prime/Prime-Plus	Free of Defects
49200	Printer Paper (rolls: 5/pkg) (small-style)	Free of Defects

Electro-Mechanical Components & Assemblies

**\*Whichever comes first.**

**NOTE: THE WARRANTED USE EXPRESSED ABOVE IS ONLY VALID IF IT OCCURS**

**PRIOR TO THE "USE BEFORE DATE" LISTED ON THE PACKAGE LABEL.**





## **CERTIFICATE OF COMPLETION**

*This is to certify that*

*Victor Meleca*

*has successfully completed Stat Profile Prime Plus Service and Application Training.*

**April 10-11, 2023**

Date of Training

**Chişinău / Moldova**

Location of Training

A blue ink signature of Huseyin Dibekkaya, consisting of a stylized, cursive script.

**Huseyin Dibekkaya**

Support Training Program Facilitator  
International Regional Support Manager

# CERTIFICATE

Mr. Sergey Sorokovitsch  
actively and successfully participated

in

**SERVICE AND APPLICATION  
TRAINING**

for

**Thrombolyzer Systems**

from 26<sup>th</sup> November to 30<sup>th</sup> November 2012

location

Kommanditgesellschaft  
Behnk Elektronik GmbH & Co.  
Hans-Böckler-Ring 27  
22851 Norderstedt  
Germany



Holger Behnk, Director

COAGULATION

**EasyBloodGas™ analyzer**  
**EasyLyte® analyzer**

**EasyElectrolytes® analyzer**  
**EasyStat® analyzer**

# *Training Certificate*

*This is to certify that*

**Mr. Sergiu Sorocovici**

**Of GBG-MLD S.R.L.**

*has completed training for the operation and service of the*

**EasyBloodGas™ analyzer, EasyElectrolytes® analyzer, EasyLyte® analyzer and EasyStat® analyzer**

04/22/2016  
DATE



*Medica Corporation*

*David Hagopian*  
*Director of Technical Support*

**EC DECLARATION OF CONFORMITY**

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

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

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

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

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

Date: 2013/04/12



*(Signature)*

Murat Khushainov  
General Director ZAO «Vector-Best»

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

24.	Ascend-IgG-EIA-BEST	antigens	ELISA kit for determination of IgG to Ascans lumbricoides	D-3452
25.	Lambli-a-antibodies-EIA-BEST		ELISA kit for determination of IgG, IgM and IgA to Lambli-a antibodies	D-3552
26.	Lambli-a-IgM-EIA-BEST		ELISA kit for determination of IgM to Lambli-a antibodies	D-3554
27.	Lambli-a-antigen-EIA-BEST		ELISA kit for determination of Lambli-a antigen	D-3556
28.	Helicobacter pylori-Caga-antigen-EIA-BEST		ELISA kit for determination of total antibodies to Caga Helicobacter pylori	D-3752
29.	ISH-EIA-BEST		ELISA kit for determination of concentration of thyroid-stimulating hormone	X-3952
30.	T3 total-EIA-BEST		ELISA kit for determination of concentration of total triiodothyronine	X-3954
31.	T4 total-EIA-BEST		ELISA kit for determination of concentration of total thyroxine	X-3956
32.	Anti-TPO-EIA-BEST		ELISA kit for determination of antibody concentration to thyroperoxidase	X-3968
33.	PAPP-A-EIA-BEST		ELISA kit for determination of concentration of pregnancy-associated plasma protein A	D-4160
34.	Mycoplasma hominis-IgG-EIA-BEST		ELISA kit for determination of IgG to Mycoplasma hominis	D-4352
35.	Mycoplasma hominis-IgA-EIA-BEST		ELISA kit for determination of IgA to Mycoplasma hominis	D-4356
36.	Mycoplasma pneumoniae-IgG-EIA-BEST		ELISA kit for determination of IgG to Mycoplasma pneumoniae	D-4362
37.	Mycoplasma pneumoniae-IgM-EIA-BEST		ELISA kit for determination of IgM to Mycoplasma pneumoniae	D-4366
38.	Vedochmean - CHF - IgG		ELISA kit for determination of IgG to Crimsean-Congo hemorrhagic fever virus	D-5052
39.	Vedochmean - CHF - IgM		ELISA kit for determination of IgM to Crimsean-Congo hemorrhagic fever virus	D-5054
40.	CEA-EIA-BEST		ELISA kit for determination of coposulation of carcinoembryonic antigen	T-8454
41.	AFP-EIA-BEST		ELISA kit for determination of concentration of Alpha-Fetal Protein	T-8456
42.	CA-125-EIA-BEST		ELISA kit for determination of concentration of oncomarker CA-125	T-8466
43.	CA 19-9-EIA-BEST		ELISA kit for determination of concentration of CA 19-9	T-8470
44.	CA 15-3-EIA-BEST		ELISA kit for determination of concentration of oncomarker CA 15-3	T-8472
45.	NSE-EIA-BEST		ELISA kit for determination of concentration of neuron specific enolase	T-8476

46.	Ferritin-EIA-BEST		ELISA kit for determination of concentration of ferritin	T-8552
47.	IgE total-EIA-BEST		ELISA kit for determination of concentration of total IgE	A-8660
48.	IgG total-EIA-BEST		ELISA kit for determination of concentration of total IgG	A-8662
49.	IgM total-EIA-BEST		ELISA kit for determination of concentration of total IgM	A-8664
50.	IgA total-EIA-BEST		ELISA kit for determination of concentration of total IgA	A-8666
51.	Gamma-Interferon-EIA-BEST		ELISA kit for determination of concentration of gamma-interferon	A-8752
52.	Interleukine-4-EIA-BEST		ELISA kit for determination of concentration of interleukine-4	A-8754
53.	Alpha-TNF-EIA-BEST		ELISA kit for determination of concentration of alpha-tumor necrosis factor	A-8756
54.	Alpha-Interferon-EIA-BEST		ELISA kit for determination of concentration of alpha-interferon	A-8758
55.	Interleukine-6-EIA-BEST		ELISA kit for determination of concentration of interleukine-6	A-8768
56.	Interleukine-2-EIA-BEST		ELISA kit for determination of concentration of interleukine-2	A-8772
57.	Procalcitonin-EIA-BEST		ELISA kit for determination of concentration of procalcitonin	A-9004
58.	NTproBNP-EIA-BEST		ELISA kit for determination of concentration of N-terminal prohomone of brain natriuretic peptide	A-9102
59.	Troponin I-EIA-BEST		ELISA kit for determination of concentration of troponin I	A-9106

# CERTIFICATE

## ELECTROMAGNETIC COMPATIBILITY

Applicant : **Vital Scientific B.V.**  
Contact person : **Mrs. C. v.d. Broek**  
Address : **Van Rensselaerweg 4**  
Postal code, Place : **6956 AV Spankeren/Dieren**  
Country : **The Netherlands**

Manufacturer : **Vital Scientific B.V.**  
Address : **Van Rensselaerweg 4**  
Postal code, Place : **6956 AV Spankeren/Dieren**  
Country : **The Netherlands**

Electrical apparatus : **Clinical Analyser**  
Trademark : **Elitech Clinical Systems**  
Type designations : **Flexor EL200, Selectra ProM**

Environment : **Laboratory**

**EN 61326-1:2006** : Equipment for measurement, control and laboratory use  
**EN 61326-2-6:2006** : Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: particular requirements – In vitro diagnostic (IVD) medical equipment, from which:

**EN 55011:2007** : Emission - Class A  
**+A2:2007**

**EN 61000-3-2:2006** : Limit for harmonic currents emissions  
**EN 61000-3-3:1995** : Limitation of voltage fluctuations and flicker  
**+A1:2001+A2:2005**

**EN 61000-4-2:1995** : Electrostatic discharge (ESD) immunity  
**A1:1998+A2:2001**

**EN 61000-4-3:2006** : Radiated Electro-Magnetic field immunity  
**+A1:2008**

**EN 61000-4-4:2004** : Electrical fast transient (EFT) immunity  
**EN 61000-4-5:2006** : Surge transient immunity  
**EN 61000-4-6:2007** : Conducted Radio-Frequency disturbances immunity  
**EN 61000-4-8:1993** : Power frequency magnetic field immunity  
**+A1:2001**

**EN 61000-4-11:2004** : Voltage dips and interruptions immunity

The undersigned declares that the described product meets the requirements of the mentioned standards, based on a non-recurrent examination. The test results lay down in our test reports with reference 2129388.0501-QUA/EMC and 2136226.0501-QUA/EMC.

KEMA Quality B.V.  
(Notified Body EMC)  
Arnhem, September 20, 2010

A.T. van der Meijden  
Certification Manager EMC



Certificate nr. **2136226.0551-QUA/EMC**

Integral publication of this certificate and adjoining reports is allowed.

KEMA Quality B.V. Utrechtseweg 310, 6812 AR Arnhem P.O. Box 5185, 6802 ED Arnhem The Netherlands  
T +31 26 3 56 20 00 F +31 26 3 52 58 00 www.kemaquality.com Registered Arnhem 09085396



# Сертификат соответствия

Настоящий сертификат удостоверяет, что организация

**АО «Вектор-Бест»**

Российская Федерация, 630117, г. Новосибирск, ул. Арбузова, 1/1

подтвердила соответствие Системы Менеджмента Качества требованиям

**ISO 13485:2016**

В отношении области деятельности, представленной ниже

**Проектирование и разработка, производство и реализация медицинских изделий для диагностики in vitro (ИФА, ПЦР, клиническая биохимия)**

Номер сертификата **209535/A/0002/UK/RUS**

Сертификат с номером 0001, подтверждает, что клиент имеет одну сертифицированную площадку, которая является головным офисом или основной площадкой применительно к области, сертифицированной в URS. Сертификат с номером 0002, или более (например: xxxx/B/0002/UK/En), выдается клиенту, у которого есть более одной площадки, сертифицированной в URS, соответственно, применяется следующее заявление: "Действительность данного сертификата, зависит от действительности основного сертификата".

Начало сертификационного цикла	Номер версии	Дата окончания срока действия сертификата	Сертификационный цикл
05 октября 2022	1	04 октября 2025	1
Дата редакции	Номер редакции	Первоначальная дата выпуска сертификата	Номер схемы
06 октября 2022	1	05 октября 2022	Не применяется

Подробнее описание данных выше см. на <http://www.urs-holdings.com/logos-and-regulations>

Выпущен

От имени менеджера по сертификации





# Сертификат соответствия

Настоящий сертификат удостоверяет, что организация

**АО «Вектор-Бест»**

Российская Федерация, 630117, г. Новосибирск, ул. Пасечная, 3

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06 октября 2022	1	05 октября 2022	Не применяется

Подробное описание данных выше см. на <http://www.urs-holdings.com/logos-and-regulations>

Выпущен

От имени менеджера по сертификации

