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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

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

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

ISO 13485:2016

The quality management system is applicable to:

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

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

Digitally signed by Ceaicovschi Tudor
Date: 2022.01.26 14:46:33 EET
Reason: MoldSign Signature
Location: Moldova

Certificate Number:
9362-8

Initial Certification Date:
March 28, 2012

Date of Certification Decision:
March 24, 2021

Issuing Date:
March 27, 2021

Valid Until:
March 27, 2024

ISO 13485:2016 CERTIFICATION ™
Intertek

SCC Accredited CB-MS
OCSM Accrédité CCN ™

Calin Moldovean
President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

intertek
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CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Medica Corporation

Main Site: 5 Oak Park Drive

Bedford, Massachusetts 01730 United States

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

ISO 13485:2016

The quality management system is applicable to:

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

Certificate Number:
0082581-01

Initial Certification Date:
2009-04-17

Certificate Issue Date:
2019-01-01

Certificate Expiry Date:
2021-04-16

SCC Accredited CB-MS
OCSM
Accrédité CCN

Calin Moldovean
President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

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

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, Na/K/Cl/Ca/Li
EasyElectrolytes and accessories per attachment	EasyElectrolytes Na/K/Cl, Na/K/Li

Manufacturer

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

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 the corresponding national laws of the Member States.

Place and Date: Bedford, Massachusetts, USA, September 27, 2018

Signature:

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

EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2004	EasyLyte Na/K Analyzer	21 07 11 02
2014	EasyLyte Plus Na/K/Cl Analyzer	21 07 11 02
2015	EasyLyte Lithium Na/K/Li Analyzer	21 07 11 02
2016	EasyLyte Calcium Na/K/Ca/pH Analyzer	21 07 11 02
2021	EasyLyte Na/K/Cl/Li Analyzer	21 07 11 02
2030	EasyLyte EXPAND Analyzer, Na/K/Cl/Ca-Li	21 07 11 02
2070	EasyLyte EasySampler	21 07 11 02
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 Reference Electrode	11 04 04 01
2258	EasyLyte Membrane Assembly	21 07 11 02
2120	EasyLyte Na/K 800 ml Solutions Pack	11 04 04 02
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 04 04 02
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 04 04 02
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 04 04 02
2028	EasyLyte Na/K/Cl/Li 400mL Solution Pack	11 04 04 02
2109	EasyLyte Na/K 400mL Solutions Pack	11 04 04 02
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 04 04 02
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 04 04 02
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 04 04 02
2026	EasyLyte Na/K/Cl/Li 800mL Solution Pack	11 04 04 02
2124	EasyLyte Na/K/Cl/Ca-Li 800ml Solutions Pack	11 04 04 02
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 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 07 11 02
2108	EasyLyte Solutions Valve	21 07 11 02
2107	EasyLyte Sample Probe	21 07 11 02
2257	EasyLyte Sample Detector	21 07 11 02

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code
2104	EasyLyte Tubing Kit	21 07 11 02
2100	EasyLyte Calcium Tubing Kit	21 07 11 02
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 07 11 02
2541	EasyLyte Printer Paper (3 rolls)	21 07 11 02
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 07 11 02
2596	EasyLyte Sample Cups 2.0mL (500)	21 07 11 02
10745	Anti-Evaporation Caps (500)	21 07 11 02
2293	EasyLyte Capillary Tubes	21 07 11 02
2590	EasyLyte Capillary Adaptor Kit	21 07 11 02
2292	EasyLyte Capillary Adaptor Cleaning Kit	21 07 11 02
2578	EasyLyte Red Dye Test Solution (50mL)	11 30 01 11
2572	EasyLyte Troubleshooting Kit	21 07 11 02
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 07 11 02
2105	EasyLyte Quarterly Operating Kit	21 07 11 02
2095	EasyLyte Maintenace Kit	21 07 11 02
2076	EasyLyte Sample Tray	21 07 11 02
2074	EasyLyte Sample Cup Retainer Ring	21 07 11 02
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 07 11 02
2934	EasyLyte Barcode Reader Kit	21 07 11 02

EasyElectrolytes Accessories

Catalog No.	Accessory	EDMA Code
4002	EasyElectrolyte Na/K/Cl Analyzer	21 07 11 02
4003	EasyElectrolyte Na/K/Li Analyzer	21 07 11 02
4102	Reagent Module, Na/K/Cl	11 04 04 02
4103	Reagent Module, Na/K/Li	11 04 04 02
7205	EasyElectrolyte/EasyStat Na+ Electrode	11 04 01 07
7206	EasyElectrolyte/EasyStat K+ Electrode	11 04 01 06
4203	EasyElectrolyte Cl- Electrode	11 04 01 03
4204	EasyElectrolyte Li+ Electrode	11 04 01 04
6204	EasyElectrolyte/EasyStat/EasyBloodGas Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	EasyStat/EasyBloodGas/EasyElectrolyte Red Test Dye Solution	11 30 01 11
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	Bi-Level Quality Control Kit	11 50 02 04
2815	Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Na/K/Cl Demonstration Kit	21 07 11 02
4406	EasyElectrolyte Na/K/Li Demonstration Kit	21 07 11 02
4404	EasyElectrolyte Capillary Tube Kit	21 07 11 02
4306	EasyElectrolyte Sampler	21 07 11 02
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 02
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 02
4506	EasyElectrolyte Sensor Module	21 07 11 02
4507	EasyElectrolyte Valve Module	21 07 11 02
4508	EasyStat/EasyBloodGas/EasyElectrolyte Compression Plate	21 07 11 02
7302	Probe Wipers	21 07 11 02
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 07 11 02
4539	EasyElectrolyte Sensor Module, Li+	21 07 11 02
6537	EasyElectrolyte/EasyStat/EasyBloodGas Serial Cable, 9-pin	21 07 11 02
6520	EasyElectrolyte/EasyStat/EasyBloodGas Barcode Reader Kit	21 07 11 02

MEDICA

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

Products For Health Care

EasyStat Analyzer Material Safety Data Sheet (MSDS)

December 7, 2015

Attention: Safety Officer/MSDS Requestor

In the table below is a list of chemicals/solutions required to operate and maintain the EasyStat analyzer. This list identifies which solutions require and do not require a Material Safety Data Sheet (MSDS).

According to Occupational Safety and Health Administration (OSHA) regulations, substances containing more than 1% of a hazardous material or more than 0.1% of an extremely hazardous material require the availability of a Material Safety Data Sheet (MSDS). If a Material Safety Data Sheet (MSDS) is required, it will accompany this memo.

Products in the table below that do not require a Material Safety Data Sheet (MSDS) should be handled with care and avoid contact with skin. If contact occurs, wash exposed area with plenty of water. As a reference, refer to the product labels for contents of active ingredients.

NOTE: Dispose of chemicals in accordance with local, state and federal regulations.

Product Description	Catalog Number(s)	MSDS Required	Chemical Substance
Reagent Module	7101	No	Non-hazardous material
Daily Cleaning Solution Kit	2118	Yes	Pepsin (powder)
Quality Control Kits	6303, 6304, 6305, 7309	No	Non-hazardous material
EasyStat Electrodes	6201, 6202, 6203, 6204, 7205, 7206, 7207, 7208	No	Non-hazardous material
Red Test Dye Solution	6402	No	Non-hazardous material
Troubleshooting Kit	7301	No	Non-hazardous material

On Behalf of Medica Corporation

P. MacGris

Photios Makris
Director of Regulatory Affairs

AMERICAN LABORATORIES INCORPORATED

SAFETY DATA SHEET

SECTION 1: Identification

Product Identifier:	Pepsin 1:3000 Powder
Other Identity:	None
Recommended Use:	Food Additive/Dietary Supplement
Supplier:	American Laboratories, Inc.
Supplier Address:	4410 South 102nd St. Omaha, NE 68127
Supplier Phone:	1-402-339-2494
Emergency Phone:	1-402-339-2494 Monday - Friday 8:00 a.m. to 5:00 p.m. CST

SECTION 2: Hazard Identification

Hazard Class:

Skin irritant Category 2
Eye irritant Category 2A
Skin sensitizer Category 1B
Respiratory sensitizer Category 1B

Signal Word: Danger

Hazard Statements:

Causes mild skin irritation
Causes eye irritation
May cause an allergic skin reaction
May cause allergy or asthma symptoms or breathing difficulties if inhaled

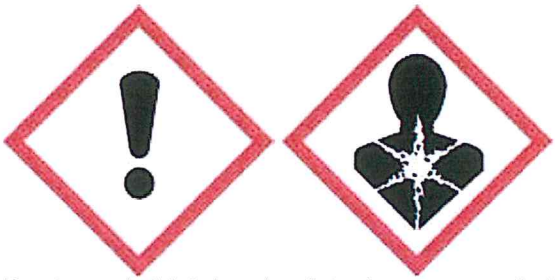
Precautionary Statements:

IF ON SKIN: In case of contact with skin, wash skin with soap and water. Remove contaminated clothing and wash.

IF IN EYES: In case of contact with eyes, flush eyes with low pressure water for at least 15 minutes. If irritation develops, seek medical attention.

IF INHALED: Avoid breathing dust. In case of inadequate ventilation wear respiratory protection. If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. May cause sensitization by inhalation in hypersensitive individuals. Avoid dust generation.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Hazard Symbols:



Other Hazards:

If extremely high levels of dust are generated in ambient air, material can support combustion.

SECTION 3: Composition/Information on Ingredients

Pepsin	CAS Number: 9001-75-6	% by weight: 15 – 30%
Lactose	CAS Number: 64044-51-5	% by weight: 70 – 85%

SECTION 4: First-aid Measures

First Aid Eye:	In case of contact with eyes, flush eyes with low pressure water for at least 15 minutes. If irritation develops, seek medical attention.
First Aid Skin:	In case of contact with skin, wash skin with soap and water. Remove contaminated clothing and wash.
First Aid Ingestion:	If swallowed, rinse mouth and throat thoroughly with tap water. Drink water.
First Aid Inhalation:	If inhaled remove from contaminated area to fresh air. Report situation. Seek medical attention if allergic response is exhibited.
First Aid Advice:	The allergic symptoms are such as runny nose, cough, sneeze, languor, slight attack of fever. Contact with powder causes irritation to sensitive skin and eyes. Any person who experiences any allergic or sensitive reactions to this powder should refrain from handling it again.

SECTION 5: Fire-Fighting Measures

Fire Fighting Extinguishing Media:	Water, foam, dry chemical, carbon dioxide
Fire Fighting Chemical Hazards:	May cause allergic respiratory reaction
Fire Fighting Protective Actions:	Not available

SECTION 6: Accidental Release Measures

For non-emergency personnel:	No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing dust. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment (see section 8).
For emergency personnel:	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.
Environmental precautions:	Avoid dispersal of spilled material.
Containment:	If a spill occurs: Spilled product should be removed immediately to avoid formation of dust. Vacuum or gently moisten with water and collect into a sealable container for disposal. Flush spill area with plenty of water (low pressure) into approved sewer. Avoid formation of aerosols and dusts. Ensure sufficient ventilation. Wash contaminated clothing.
Clean up:	Not available
Other issues:	Not available

SECTION 7: Handling and Storage

Handling advice:	Never handle powder without appropriate personal protective equipment in accordance with Section 8. Avoid formation of dust. Avoid splashing and high pressure washing. Ensure good ventilation of the room when handling this product.
Hygiene:	Maintain good conditions of industrial hygiene
Storage:	Store in tightly closed poly-liners within a sealed container in an odor-free environment, where normal temperatures do not exceed 30°C and normal relative humidity is not more than 70%.
Conditions to avoid:	Not available
Control:	Not available
Maintain:	Not available
Other advice:	Not available

SECTION 8: Exposure Controls/Personal Protection

Occupational exposure limits:	Not available
Biological limit values:	Not available
Control banding:	Not available
Appropriate engineering controls:	Adequate ventilation required for dusty conditions.
Eye/face protective equipment:	Protective glasses or eye shield recommended.
Skin protection:	Impermeable gloves recommended.
Respiratory protection:	None required under usual condition of use. However, if breathable dusts are present, a suitable dust mask is recommended (refer to NIOSH Criteria Guides to determine appropriate unit).
Thermal protection:	Not available
Special requirements:	Not available

SECTION 9: Physical and Chemical Properties

Appearance:	Off-White to Light Yellow Powder
Odor:	Characteristic enzyme odor
Odor Threshold:	Not available
pH:	3.0 – 4.5
Melting point/freezing point:	Not available
Initial boiling point and boiling range:	Not available
Flash point:	Not available
Evaporation rate:	Not available
Flammability (solid, gas):	Not available
Upper/lower flammability or explosive limits:	Not available
Vapor pressure:	Not available
Vapor density:	Not available
Relative density:	Not available
Solubility:	Soluble
Partition coefficient: n-octanol/water:	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
Viscosity:	Not available

SECTION 10: Stability and Reactivity

Reactivity:	Not available
Stability:	Stable
Hazardous reactions:	Not available
Conditions to avoid:	Not available
Incompatible materials:	Not available
Hazardous decomposition products:	Not available

SECTION 11: Toxicological Information

Acute toxicity:	Not available
Skin corrosion/irritation:	Skin irritant Category 2
Serious eye damage/irritation:	Eye irritant Category 2A
Respiratory or skin sensitization:	Respiratory sensitizer Category 1B, Skin sensitizer Category 1B
Germ cell mutagenicity:	Not available
Carcinogenicity:	Not classified as a carcinogen by IARC, OSHA, or NTP
Reproductive toxicity:	Not available
STOT-single exposure:	Not available
STOT-repeated exposure:	Not available
Aspiration hazard	Not available

SECTION 12: Ecological Information

Toxicity:	Not available
Persistence and degradability:	Product is readily biodegradable.
Bioaccumulative potential:	Not available
Mobility in soil:	Not available
Other adverse effects:	Not available

SECTION 13: Disposal Considerations

Disposal Methods: No special disposal method required, except that in accordance with current local authority regulations

SECTION 14: Transport Information

UN Number:	Not classified
UN Proper Shipping Name:	Not classified
Transportation Hazard Class:	Not classified
Packing Group:	Not classified
Transport Environmental Hazard:	Not classified
Transport Special Precautions:	Not classified
MARPOL:	Not classified

SECTION 15: Regulatory Information

The active ingredient and all components of the enzyme preparation are listed on the TSCA Inventory.

SECTION 16: Other Information

ALTHOUGH THE INFORMATION AND RECOMMENDATIONS SET FORTH IN THIS SHEET ARE BELIEVED TO BE CORRECT AS OF THE DATE HEREOF, AMERICAN LABORATORIES, INC. MAKES NO REPRESENTATION AS TO THE COMPLETENESS OR ACCURACY OF SUCH INFORMATION AND RECOMMENDATIONS. AMERICAN LABORATORIES, INC. SHALL IN NO EVENT BE RESPONSIBLE FOR DAMAGES OF WHATSOEVER NATURE DIRECTLY OR INDIRECTLY RESULTING FROM THE PUBLICATION OR USE OF OR RELIANCE UPON SUCH INFORMATION AND RECOMMENDATIONS. YOU ARE ENCOURAGED TO ADVISE ANYONE WORKING WITH OR EXPOSED TO SUCH PRODUCTS OF THE INFORMATION CONTAINED HEREIN.

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www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 016316 0022 Rev. 00

Manufacturer:

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen
GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

Report No.: 713175396

Valid from: 2020-08-10
Valid until: 2025-08-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-08-10

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 016316 0022 Rev. 00

Device Group:	Z120109 - ELECTROSURGERY INSTRUMENTS
Classification:	IIb
Intended Purpose:	Generation of electrical power for monopolar and bipolar cutting and coagulation on tissue structures in surgical operations
Device Group:	K020101 - ELECTROSURGICAL INSTRUMENTARY, MONO- AND BIPOLAR, SINGLE-USE
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	K020102 - ELECTROSURGICAL PADS AND CABLES
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	K020480 - ARGON GAS SURGICAL DEVICES - ACCESSORIES
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	L180201 - SCISSORS, "OPEN SKY" ELECTROSURGICAL, REUSABLE
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	L180301 - HANDPIECES, "OPEN SKY" ELECTROSURGICAL, REUSABLE
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	L180401 - FORCEPS, "OPEN SKY" ELECTROSURGICAL, REUSABLE
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	L180402 - FORCEPS, ELECTROSURGICAL ENDOTHERAPY, REUSABLE

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BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 016316 0022 Rev. 00

Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	L180602 - ELECTRODES, ELECTROSURGICAL ENDOTHERAPY, REUSABLE
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	K020401 - ARGON GAS SURGICAL INSTRUMENTARY, SINGLE-USE
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Device Group:	L180601 - ELECTRODES, "OPEN SKY" ELECTROSURGICAL, REUSABLE
Classification:	IIb
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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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 016316 0021 Rev. 01

Holder of Certificate: **BOWA-electronic GmbH & Co. KG**
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen
GERMANY

Certification Mark:

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

Scope of Certificate: **Design and development, production and distribution of sterile and non-sterile medical devices:
Electrosurgical Units and Accessories,
Argon Coagulation Units and Accessories,
Electrode Handles,
Active Electrodes and Instruments,
Monopolar and Bipolar Forceps,
Endoscopic and Laparoscopic Instruments,
Instruments for Vessel Sealing,
Neutral Electrodes and
Bipolar Scissors**

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 016316 0021 Rev. 01

Report No.: 713198949

Valid from: 2021-02-22
Valid until: 2022-02-28

Date, 2021-02-22

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 016316 0021 Rev. 01

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):

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10, 72810 Gomaringen, GERMANY

Design and development, production and distribution of sterile and non-sterile medical devices:
Electrosurgical Units and Accessories,
Argon Coagulation Units and Accessories,
Electrode Handles,
Active Electrodes and Instruments,
Monopolar and Bipolar Forceps,
Endoscopic and Laparoscopic Instruments,
Instruments for Vessel Sealing and
Bipolar Scissors

Design and development and distribution of sterile and non-sterile medical devices:
Neutral Electrodes

BOWA Polska Sp. zo. o.
Zlotkowo, ul. Obornicka 10, 62-002 Suchy Las, POLAND

Production of sterile and non-sterile medical devices:
Instruments for Vessel Sealing and
Neutral Electrodes

./.

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

TÜV®

EasyLyte EasyBloodGas EasyStat

Training Certificate

This is to certify that

Sorocovici Sergiu

Of Global Biomarketing Group

has completed training for the operation and service of the EasyLyte, EasyBloodGas, and EasyStat analyzers.

November 25, 2004

Date

MEDICA CORPORATION CORPORATE SEAL MASSACHUSETTS 1965

MEDICA

Randall Rollins

Signed: Randall Rollins
Technical Service Manager

Declaration of Conformity

We: **Vital Scientific B.V.**
Van Rensselaerweg 4
6956 AV Spankeren/Dieren
The Netherlands

Declare under sole responsibility that the product indicated below (including all spares and accessories) and to which this declaration relates, conforms to the provisions of the EU Directive on *In Vitro* Diagnostic Medical Devices (98/79/EC) of the European Parliament and the Council of 27 October 1998. It is certified that this product is registered in accordance with the requirements of above mentioned EU Directive and carries the CE mark.

Product	**: Clinical chemistry analyzer**
Model	**: Selectra XL**
Catalog No.	**: 6002-600**
GMDN code	**: 56678 (Analyzer)**
	: 56682 (Dry ISE)

Product classification

Products for self declaration (also referred to as: "Other Devices")

Conformity assessment procedure

In accordance with Annex III of the IVDD

The product (including all spares and accessories) may be marketed without any restrictions within the following countries and regions:

- The Netherlands (NL)
- All member states of the European Union (EU)
- All other states that are part of the European Economic Area (EEA)

Spankeren, February 2011

A.Altink
Managing Director

CE	Declaration of Conformity	ELITechGroup VITAL SCIENTIFIC

List of applied (harmonized) standards

Applied standards		
Safety	IEC 61010-1:2001 Second edition	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements
	IEC 61010-2-081:2001 First edition	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
	IEC 61010-2-101:2002 First edition	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical devices
EMC	EN 61326-1:2006	Equipment for measurement, control and laboratory use
	EN 61326-2-6:2005	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment
	EN55011:2007	Emission – class A
	EN 61000-3-2:2006	Limit for harmonic currents emissions
	EN 61000-3-3:1995 +A1:2001, +A2:2005	Limitation of voltage fluctuations and flicker
	EN 61000-4-2:1995 +A1:1998, +A2:2001	Electrostatic discharge (ESD) immunity
	EN 61000-4-3:2006	Radiated electromagnetic field immunity
	EN 61000-4-4:2004	Electrical fast transient (EFT) immunity
	EN 61000-4-5:2006	Surge transient immunity
	EN 61000-4-6:1996 +A1:2001	Conducted Radio-Frequency disturbances immunity
	EN 61000-4-11:2004	Voltage dips and interruptions immunity
User Manual	EN 591:2001	In vitro diagnostic systems – Requirements for user manuals for in vitro diagnostic instruments for professional use.
Performance	EN 13612:2003	Performance evaluation of IVD medical devices
Symbols	EN 980:2003	Graphical Symbols for use in the labeling of medical devices
Risk analysis	ISO 14971:2007	Medical devices - Application of risk management to medical devices
Quality systems	ISO 9001:2008	Quality systems - Model for quality assurance in design, development, production, installation and servicing.
	ISO 13485:2003	Medical devices—Quality management systems—Requirements for regulatory purposes.