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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Medica Corporation

(FIN F002402)

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

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

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

ISO 13485:2016

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

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

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

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

The management system is applicable to:

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

Digitally signed by Ceaicovschi Tudor
Date: 2023.08.25 16:47:45 EEST
Reason: MoldSign Signature
Location: Moldova

Certificate Number:
0089217-01

Initial Certification Date:
2019-04-19

Date of Certification Decision:
2022-03-24

Certification Effective Date:
2022-04-18

Certification Expiry Date:
2025-04-18

ISO 13485:2016 CERTIFICATION™

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean
President, Business Assurance

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

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

Declaration of Conformity CE

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

Manufacturer

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

Representative

EC REP Emergo Europe, 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

EasyBloodGas and EasyStat Accessories

Catalog No.	Accessory	EDMA Code
6001	EasyBloodGas Analyzer	21 07 11 01
7001	EasyStat Analyzer	21 07 11 03
7017	EasyStat Analyzer	21 07 11 03
6201	EasyStat/EasyBloodGas pH Electrode	11 70 31 04
6202	EasyStat/EasyBloodGas pCO2 Electrode	11 70 31 04
6203	EasyStat/EasyBloodGas pO2 Electrode	11 70 31 04
6204	EasyStat/EasyBloodGas/EasyElectrolyte Reference Electrode	11 04 04 01
6101	EasyBloodGas Reagent Module	11 70 31 50
6301	EasyBloodGas Troubleshooting Kit	21 04 10 01
6303	EasyQC Level 1 Blood Gas and Electrolyte Quality Control	11 70 31 50
6304	EasyQC Level 2 Blood Gas and Electrolyte Quality Control	11 70 31 50
6305	EasyQC Level 3 Blood Gas and Electrolyte Quality Control	11 70 31 50
2118	Daily Cleaning Solution	11 01 01 27
6402	Red Test Dye Solution	11 30 01 11
6503	EasyBloodGas Capillary Tube Kit	21 07 11 01
6603	EasyBloodGas Demonstration Kit	21 07 11 01
6306	EasyBloodGas Sampler	21 07 11 01
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 03
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 03
6506	EasyBloodGas Sensor Module	21 07 11 01
6507	EasyBloodGas Valve Module	21 07 11 03
6508	Compression Plate	21 07 11 03
6537	Serial Cable, 9-pin	21 07 11 03
6520	Barcode Reader Kit	21 07 11 03
7101	EasyStat Reagent Module	11 70 31 10
7205	EasyElectrolyte/EasyStat Na Electrode	11 04 01 07
7206	EasyElectrolyte/EasyStat K Electrode	11 04 01 06
7207	EasyStat Ca Electrode	11 04 01 02
7208	EasyStat Cl Electrode	11 04 01 03
7301	EasyStat Troubleshooting Kit	21 07 11 03
7309	Bi-Level Hematocrit Quality Control	11 50 02 90
7603	EasyStat Demonstration Kit	21 07 11 03
7303	EasyBloodGas/EasyStat Capillary Tube Kit	21 07 11 03
7306	EasyStat Sampler	21 07 11 03
7304	EasyStat Pump Tube	21 07 11 03
7506	EasyStat Sensor Module	21 07 11 03
7302	Probe Wipers	21 07 11 03

MEDICA

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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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Products For Health Care

Declaration of Conformity CE

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

Manufacturer

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

Representative

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NL-2513 BH The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

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

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

Signature:

Name: Photios Makris

Title: Director of Regulatory Affairs

EasyBloodGas and EasyStat Accessories

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

EasyElectrolyte Accessories

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

EasyLyte Accessories

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

EasyLyte Accessories, continued

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

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

MEDICA

EasyStat®

medicacorp.com

EasyStat®

easy inside and out

- Medica's EasyStat analyzer measures pH, PCO_2, PO_2, Na^+, K^+, Ca^{++} or Cl^- and Hct, and calculates additional parameters. Patient parameters, including FIO_2, patient ID, patient temperature, $\%FIO_2$, drawing site and other information can be entered using the digital keypad and integrated with patient results. Measured and calculated results are displayed and printed

- EasyStat focuses on the laboratory's need to deliver sample results economically and efficiently

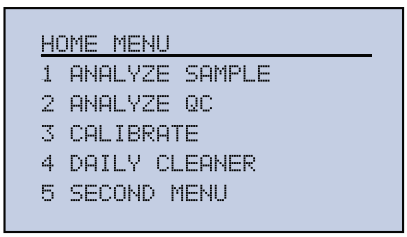
- The sophistication and performance required by today's busy, demanding health care environment have been packaged in a new compact format with a small footprint to save space

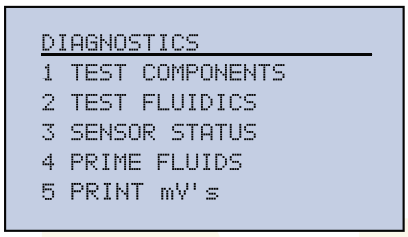
- Liquid calibrants are packaged in a convenient reagent module, eliminating gas tanks

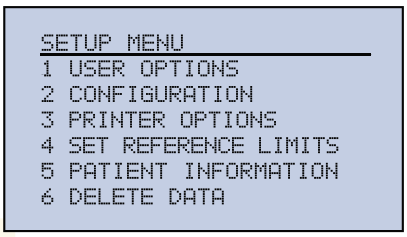
- All components are combined into three simple modules, easily accessible by the user. Routine maintenance is limited to the replacement of electrodes and a single pump tube.

- Simple menus guide the user through analyzer operation

- Unique electrode design with no membranes to change, combined with a reagent module with over 1,000-sample capacity ensure economical operation and low cost per sample



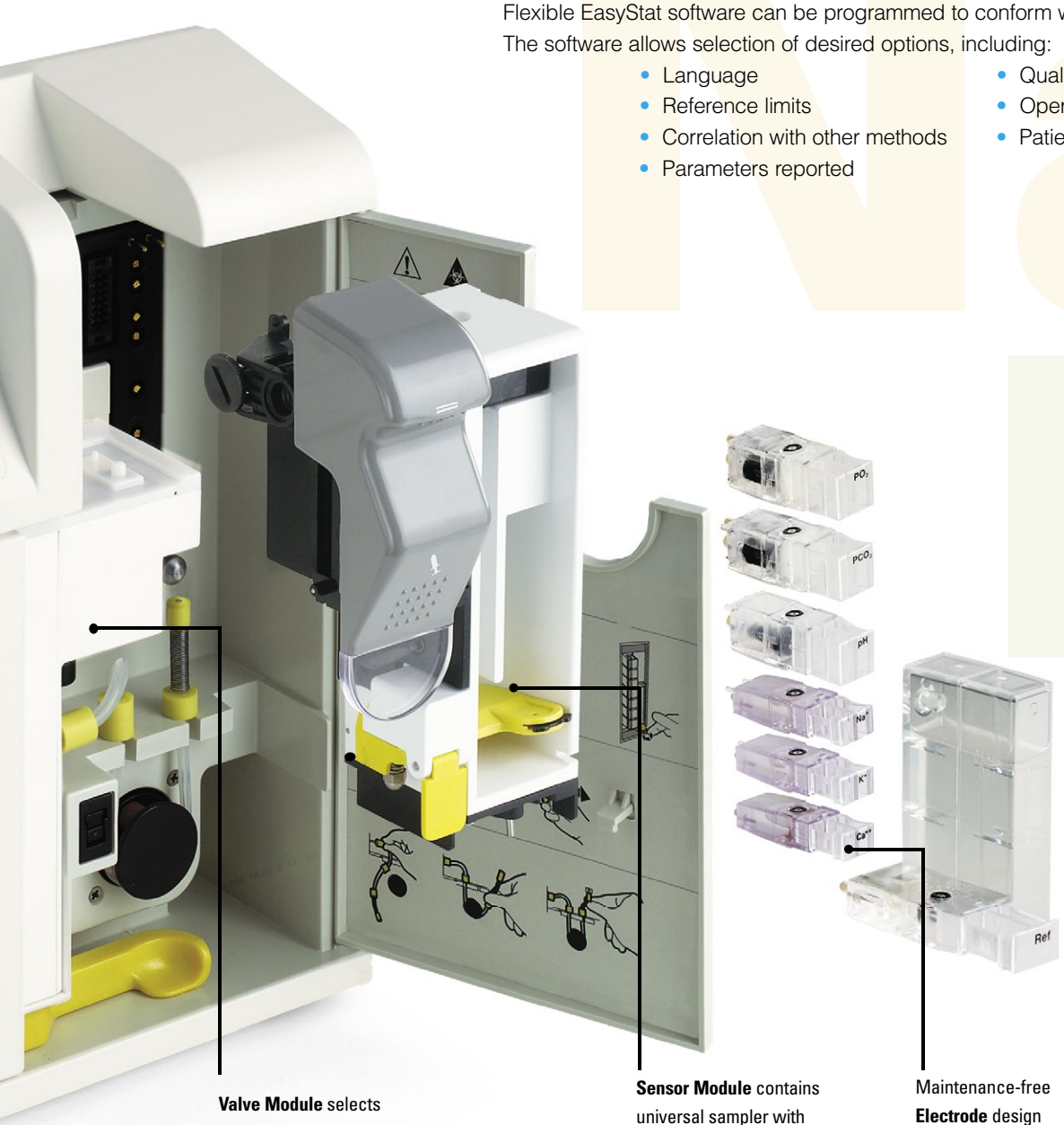




Flexible Software

Flexible EasyStat software can be programmed to conform with the lab's established practices. The software allows selection of desired options, including:

- Language
- Reference limits
- Correlation with other methods
- Parameters reported
- Quality Control limits
- Operator ID
- Patient data



Valve Module selects calibrants and rinse solutions

Sensor Module contains universal sampler with self-wiping probe for convenience and safety

Maintenance-free **Electrode** design permits fast, fail-safe installation

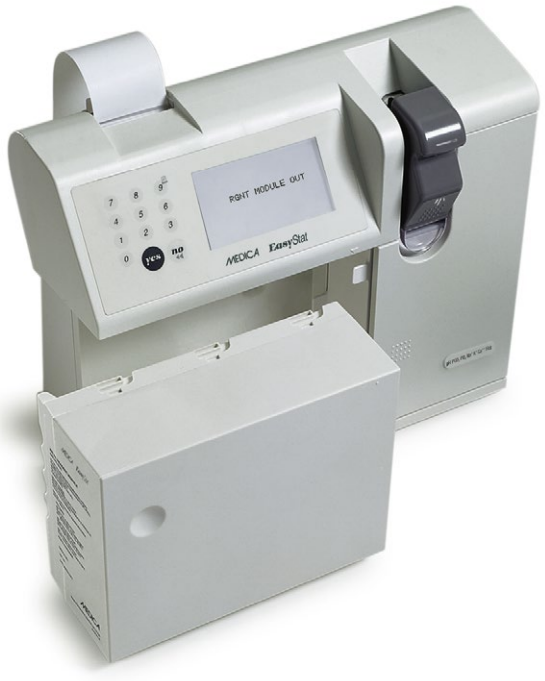
...*Easy* inside

EasyStat can be used and maintained by anyone, anytime, anywhere

- Removal of the three plug-in modules — Reagent Module, Sensor Module and Valve Module — is accomplished without tools.
- Medica's integral membrane design means that electrodes are disposable and require no maintenance. Electrodes snap in and out for easy replacement.
- Sample path has been simplified—only one length of pump tubing requires periodic replacement.
- Innovative design simplifies maintenance, addressing the needs of the remote laboratory which has limited access to technical service personnel. Diagnostic software displays component status, assuring quick troubleshooting. Modularity makes assembly and disassembly quick and easy. There is no need for expensive service contracts.

Comprehensive management of patient, quality control and maintenance data

- The EasyStat quality control program calculates and stores complete statistics for the last 31 days of quality control results at each of three levels. A printed Levey-Jennings chart visually identifies trends.
- The data management program compares all patient results with ranges stored in memory and flags out-of-range results. Results are stored in memory for up to 64 patients.
- Exchange of components, calibration and other events are documented for regulatory compliance.
- Bar code scanner option permits rapid, accurate input of patient, operator and QC data.



Self-contained Reagent Module contains liquid calibrants and collects all waste

...*Easy* outside

Blood gas analyzer operation has never been simpler

- The Universal Sampler adapts to both syringe and capillary samples without adaptors. The sample probe's self-wiping feature provides convenience, sample integrity and user safety.
- The simple, yes/no user-prompting menu makes rapid training of new personnel possible.

Syringe Sampling

Capillary Sampling

Compact Reagent Module for convenience, economy and safety

Bulky gas tanks are replaced with liquid, tonometered calibrants, packaged in a convenient Reagent Module that also collects waste, protecting the user from biological hazards. The EasyStat automatically tracks date code and calibrant usage with the Reagent Module's solid state memory. Operation without interruption is assured.

Portable

Light weight design with optional handle allows use in any setting.

Specifications

CLIA Classification:	Moderate complexity
Sample Type:	Whole blood
Sample Size:	120 µL Syringe mode/95 µL Capillary mode

Measured Parameters and Limits

PO_2	5 – 700 mmHg
PCO_2	5.0 – 150.0 mmHg
pH	6.500 – 8.000 pH units
Hct	10 – 70%
Na^+	80 – 200 mmol/L
K^+	1.0 – 20.0 mmol/L
Ca^{++}	0.25 – 5.00 mmol/L
Cl^-	50.0 – 150.0 mmol/L

Calculated Parameters

THb (Total Hemoglobin)	3.3 – 23.3 g/dL
pH (T) (pH temperature corrected)	
PCO_2 (T) (PCO_2 temperature corrected)	
PO_2 (T) (PO_2 temperature corrected)	
TCO_2 (Total Carbon dioxide)	0 – 50 mmol/L
HCO_3^- (Bicarbonate)	0 – 50 mmol/L
BE_b (Base Excess in blood)	-25.0 to 25.0 mmol/L
BE_{ecf} (Base Excess in extracellular fluid)	-25.0 to 25.0 mmol/L
SBC (Standard Bicarbonate)	0 – 50 mmol/L
$\%SO_{2c}$ (Oxygen Saturation)	40.0 – 100.0% (calculated at normal P50)
CtO_2 (Oxygen Content)	3.0 – 30.0 mL/dL
A-aDO_2 (Alveolar arterial oxygen gradient)	0 – 700 mmHg
RI (Respiratory Index)	0.0 – 70.0
Ca^{++} (7.4) (for 7.2<pH<7.6)	0.22 – 5.58 mmol/L

Input Parameters

Patient Temperature	(20 – 45°C)	Time Drawn	(00:00)
Hemoglobin	(3.0 – 30.0 g/dL)	Sample Source	(arterial, mixed venous, venous)
FIO_2 (Fraction Inspired Oxygen)	(10 – 100%)	Sample Type	(radial, brachial, femoral, arterial line)
Patient ID	(14 digits)		
Operator ID	(14 digits)		

Sample Temperature Control:	37.0°C ± 0.2°C
Ambient Conditions:	15–30°C (59-86°F), 500–800 mmHg (max 15 PSI) 5–85% relative humidity, non-condensing atmospheric air environment (21% O_2)
Analysis Time:	<120 seconds
Data Storage:	64 Patient results with Operator ID, Patient ID, Date and Time QC—up to 93 results for each Level (Blood Gas/Electrolytes 1, 2, 3, Hct 1, 2)
Calibration:	Automatic or On-Demand
Input/Output:	Numeric keypad, graphic display, 27 column thermal line printer, barcode reader port, RS-232 computer interface port
Power:	100/115~VAC, 50–60 Hz, 0.8 A or 220~VAC, 50–60 Hz, 0.4 A Refer to the chassis serial number label for the voltage that has been factory set on your analyzer, and for proper fuse replacement.
Size & Weight:	14.5" W x 12.5" H x 7.0" D (37cm W x 32cm H x 18cm D), 17 lbs (7.7 kg) with Reagent Module

***Cl^- Available in select countries**

Medica Corporation
5 Oak Park Drive
Bedford, MA 01730-1413
USA

USA **800 777 5983**

Global **+1 781 275 4892**

Fax **781 275 2731**

medicacorp.com

CE Medica Corporation, 5 Oak Park Drive, Bedford, MA 01730-1413 USA
EC REP Emergo Europe, Prinsessegracht 20, 2514 AP, The Hague, The Netherlands

MEDICA

Products for Health Care

EasyLyte

www.medicacorp.com

Na^+/K^+

$Na^+/K^+/Cl^-$

$Na^+/K^+/Li^+$

$Na^+/K^+/Ca^{++}/pH$

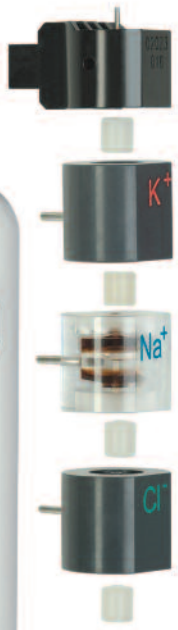
EasyLyte

easy inside and out

- **Easy to Use**
  - Simple, menu-driven, Yes/No prompted operation
  - Whole blood, serum, plasma or urine samples
  - Results printed automatically in less than 60 seconds
  - Automatic or on-demand calibration
  - Automatic probe wiping
- **Easy to Maintain**
  - All calibrants contained in convenient, disposable solutions pack
  - All waste collected in solutions pack
  - Disposable electrodes require no maintenance
  - Modular design makes maintaining analyzer simple and fast
- **Easy to Afford**
  - Low analyzer purchase price
  - Low cost per test
- **Available in four models:**
  - ***EasyLyte*** Na^+/K^+
  - ***EasyLyte PLUS*** $Na^+/K^+/Cl^-$
  - ***EasyLyte Lithium*** $Na^+/K^+/Li^+$
  - ***EasyLyte Calcium*** $Na^+/K^+/Ca^{++}/pH$


EasyLyte
EasyLyte®
Solutions Pack
Kit de solutions
Confezione di soluzioni
Lösungspackung
Embalagem de Soluções
Kit de soluciones
MEDICA

Modular, maintenance-free electrodes



Self-contained Solutions Pack contains liquid calibrants and collects all waste, eliminates sample contact

Internal printer prints patient results, calibration values, quality control data, and results summaries, flagging abnormal results

Pressing Yes or No buttons is all that is required to analyze serum, plasma or whole blood

Capillary sampler is removable and disposable

EasySampler

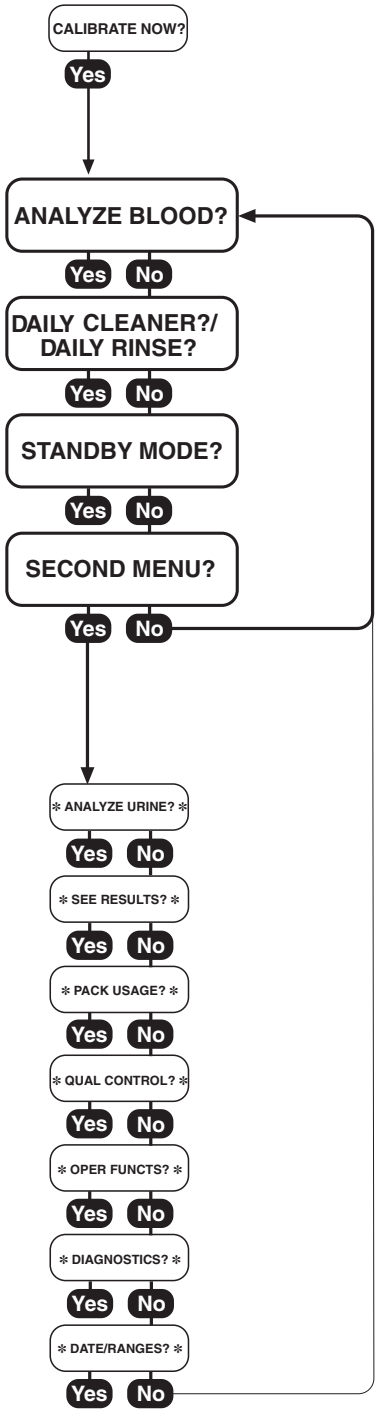
The modular EasySampler connects quickly to the EasyLyte Na/K, Na/K/Cl, and Na/K/Li analyzers, enhancing laboratory performance.

- 21 sample positions
- Dedicated Stat position
- Normal/Abnormal QC positions
- Optional auto-repeat of out-of-range values

Analyzer software insures ease of operation

Software computes quality control statistics, flags abnormal results, and monitors performance.

- Two button operation
- Automatic calibration
- User-friendly menu



Specifications

(Na^+/K^+, $Na^+/K^+/Cl^-$, $Na^+/K^+/Li^+$, $Na^+/K^+/Ca^{++}$/pH)

MEDICA
Products for Health Care

Medica Corporation
5 Oak Park Drive
Bedford, MA 01730-1413
USA

Continental US Telephone
800 777 5983

International Telephone
781 275 4892

Fax
781 275 2731

sales@medicacorp.com

www.medicacorp.com

Call for our free CD

CLIA Classification: Moderate Complexity

Sample Type: Whole Blood, Serum, Plasma or Urine

Sample Size: 100 µL Whole Blood, Serum, Plasma, 60 µL capillary or 400 µL diluted (1:10) Urine

Method: Direct measurement by Ion Selective Electrode (ISE)

Measurement Range:

Blood	**Urine**
Na^+: 20 – 200 mmol/L	Na^+: 25 – 1000 mmol/L
K^+: 0.2 – 40 mmol/L	K^+: 1.0 – 500 mmol/L
Cl^-: 25 – 200 mmol/L	Cl^-: 25 – 500 mmol/L
Li^+: 0.2 – 5.0 mmol/L	
Ca^{++}: 0.1 – 6.0 mmol/L	
pH: 6.0 – 8.0 Units	

Display Resolution: Na^+: 0.1 mmol/L K^+: 0.01 mmol/L Cl^-: 0.1 mmol/L
Li^+: 0.01 mmol/L Ca^{++}: 0.01 mmol/L pH: 0.005 units

	Na^+/K^+	$Na^+/K^+/Cl^-$	$Na^+/K^+/Li^+$	$Na^+/K^+/Ca^{++}$/pH
Analysis time (blood)	55 sec	55 sec	55 sec	60 sec
Urine Mode	Yes	Yes	Yes	No
Analysis time (urine)	90 sec	90 sec	90 sec	N/A
EasySampler	Yes	Yes	Yes	No
Capillary Samples	Yes	Yes	Yes	No

Data Storage: Patient results — up to 128 samples
QC results — up to 20 each Normal, Low, and High

Calibration: Automatic or On-Demand

Output: 128 x 64 pixel graphic display
24 column thermal printer
Serial port (RS-232), EasySampler port

Ambient Conditions: 15–32°C (60–90°F), <85% humidity

Power: 100-240 VAC 50/60 Hz, 0.8A

Size & Weight: 9.5”W x 16.5”H x 8.0”D (24 cm W x 42 cm H x 20 cm D) 13 lbs. (5.8 kg)

Adapter monopolar, Martin, for BOWA 3-Pin

Universal adapters secure possible connections

Scope of delivery

Incl. instructions for use

Product number: 901-270

Unit: 1 piece

Instrument side: 8/4 mm Martin

Device side: BOWA MEDICAL ARC 250/303

Reset selection

Inquiry

Description | Specification | Download

Adapter monopolar

The various adapters provide the transition between connection cables and electrosurgery devices as needed. Various types are available. The adapters can also be mechanically cleaned as needed. The compatibilities must be taken into account.

Scope of delivery

Incl. instructions for use

BOWA MEDICAL
BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Straße 4-10
72810 Gomaringen
Deutschland

+49 (0) 7072-6002-900
support@bowa-medical.com
https://www.bowa-medical.com/

Cable, ErgoLAP BIPOLAR, for 2-pin 28 mm, 4.5 m

RF cables for laparoscopic instruments

- Can be reused many times
- High voltage security
- Especially suitable for high loads in everyday clinical practice

Scope of delivery

Incl. instructions for use

Product number: 351-245

Unit: 1 piece

Instrument side: ErgoLAP BIPOLAR

Device side: 2 pin 28 mm

Reset selection

Inquiry

Description | Specification | Download

BOWA MEDICAL cable for connecting laparoscopic instruments

With BOWA MEDICAL cables, laparoscopic instruments can be connected to RF devices. The connection cables are specially designed for the high demands of everyday clinical practice. They have a high level of voltage security and stand out due to their longevity.

RF cables with maximum durability and reliability

When used, the monopolar cables are characterised by a long service life and reliability:
- Corrosion protection through silver-plated cable bundles and the use of components that have been tried and tested a million times
- Ideal cleaning properties thanks to the round cable shape
- Reliable contact connections through large-scale crimping technology
- Extreme durability for up to 300 reprocessing cycles through glass fibre reinforced material.

Scope of delivery

Incl. instructions for use

This is a translation of the certificate DE22/00000615

The management system of

BOWA-electronic GmbH & Co. KG

Heinrich-Hertz-Strasse 4-10, DE 72810 Gomaringen

has been assessed and certified as meeting the requirements of

ISO 14001:2015

For the following activities
Development, production, and distribution of medical devices for electrosurgery (cables, injection moulded parts, instruments, electronic assembly, toolmaking)

This certificate is valid from 22 December 2022 until 21 December 2025 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 22 December 2022

Authorised by	Authorised by
Michael Rath	ppa. Alexander Hirschhäuser
Head of Certification Body	Director KNS Germany

SGS-TÜV Saar GmbH
Am TÜV 1 66280 Sulzbach (Germany)
t +49 (0)40 30.101.361 - www.sgs-tuev-saar.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-12088-01-00

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

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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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 -

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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. 02

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

Certification Mark:

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. 02

Report No.: 713229570

Valid from: 2022-03-02
Valid until: 2025-03-01

Date, 2022-03-02

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service

Certificate

No. Q5 016316 0021 Rev. 02

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

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