

ABBOTT

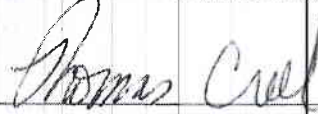
Declaration of Conformity

Certificate Identification:	1G06
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address:	Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
01G06-11	56676	ARCHITECT c8000 PROCESSING MODULE	Self-declared
09D28-03	56676	ARCHITECT cSYSTEMS ICT MODULE	Self-declared
Authorized European Representative (Name and Address)		Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany	
Storage site of technical documentation (Name and Address)		Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs	
Harmonized Standards		Listed in the Technical Documentation	

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states, and Directive 2011/65/EU the restriction of the use of certain hazardous substances in electrical and electronic equipment (ROHS).

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: 


Full Name: Thomas Creel

Position: Director, Quality Assurance

Date of Approval: 19-FEB-2019

Date Issued: 19-FEB-2019

Supersedes: June 20, 2018

Signature: 

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: 19-FEB-2019

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): 19-FEB-2019



Tel. +49 61 22 56 0
Fax +49 61 22 56 1244

Abbott GmbH & Co KG
Max-Planck-Ring 2
D- 65205 Wiesbaden
Postfach 1303, D-65011 Wiesbaden



CELL-DYN Systems

Attachment 1: List of items

CELL-DYN 1800

Equipment, Parts, Accessories

- 03H54-01 Accessory Kit (NOTE: For a list of items in the Kit, see the Accessory Kit)
- 07H79-01 Interface Specifications
- 07H78-01 Keyboard
- 92274-01 Aperture Plate WBC
- 92264-01 Aperture Plate RBC
- 28561-01 Lyse Syringe
- 04H36-01 Diluent Syringe
- 28514-01 Sample Syringe
- 21704-01 Waste Dummy Plug
- 93164-01 Sample Probe
- 54305-01 Aperture Brush
- 20005-01 Printer Cable
- 91012-01 Teal Line Filter Isolation
- 07H81-01 Bar Code Scanner
- 03H96-01 Pull Ring, Solenoid
- 99650-01 Code 39 Bar Code Labels
- 07H67-01 Lyse Cap for 996 mit container
- 09H35-01 Diluent Syringe

Accessory Kit (L/N 03H54-01)

- 1403204 Keyboard Cover
- 93501-01 Power Cord
- 5406753 Allen Wrench 3/32"
- 5406754 Allen Wrench 7/64"
- 54305-01 Aperture Brush
- 91072-01 Reagent Line Kit
- 20005-01 Printer Cable
- 9150143 Instructions for Mixing and Handling
- 93476-01 Silicon Tubing (S2)

Reagent Line Kit (L/N 91072-01)

- 03H82-01 Reagent Line Assembly, Lyse (1L)
- 03H82-01 Detergent Line Inlet Assy
- 92161-02 Waste Line Assembly
- 92163-01 Diluent Line Inlet Assembly
- 92178-01 Lyse Line Inlet Tube

Consumables

- 30005-01 OKIDATA® Graphics Paper
- 13401-01 Ribbon OKIDATA® 320
- 03H10-04 HP Printer Cartridge (Black)
- 99605-02 (International) CELL-DYN Counting Cups
- 99606-02 (International) CELL-DYN Counting Cups

DATE: 14th December 2015

TO: To whom it may concern

FROM: Paolo Mellino
Manager Regulatory Affairs Logistics
Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden-Deikenheim
Germany

SUBJECT: Classification of Instrument Parts

To whom it may concern:

Abbott GmbH & Co KG, Germany, is an authorized representative of Abbott Laboratories that is a worldwide manufacturer of medical equipment, reagents, tests, instruments, and accessories, with additional diagnostic manufacturing plants in the USA and Ireland.

The items listed in Attachment 1 are considered components of accessory kits or spare parts to the ARCHITECT and CELL-DYN instruments.

The spare parts or components of the accessory kit are qualified as part of the respective instrument following the requirements of the IVD Directive 98/79/EC. Therefore these are not considered an IVD device in their own right and do not bear a CE-mark.

For the instruments which are qualified according to the IVD Directive 98/79/EC, a Declaration of Conformity is issued by the manufacturer and the CE-mark is applied, which confirms compliance to the provisions of the directive

Yours sincerely,

P. Mellino
Paolo Mellino
Manager Regulatory Affairs Logistics



Sitz der Geschäftsstelle: Wiesbaden
Wiesbaden, HRA 4386
Präsident: Ulfendine Geesthoff
Sitz der Geschäftsstelle: Wiesbaden
Präsident: Ulfendine Geesthoff
Sitz der Geschäftsstelle: Wiesbaden
Präsident: Ulfendine Geesthoff



CELL-DYN 3700

Accessories Kit (List Number 06H88-01)

- 02H33-01 CD 3700 Interface Specification
- *1403216 Keyboard Cover
- 2005-01 6ft Interface Cable
- 21704-01 Waste Sensor Dummy Plug
- *2400502 Cord Power, 125V
- *3004908 Computer Printer Paper 8-1/2" X 11"
- *5100186 Fuse, 8 Amp T (Si-Blo)
- *5100201 Fuse Fast, 1.6 Amp
- *5405754 Allen Wrench, Hex, Short "L" 7
- 54305-01 Aperture Brush
- *5100164 Fuse, 4 Amp T (Si-Blo)
- 70048-01 Allen Wrench
- 91482-01 Reagent Line Kit
- 91484-01 Peristaltic Pump Tubing- Small
- 91485-01 Peristaltic Pump Tubing- Medium
- 9212230 Sample Aspiration Tubing (Sample Loader)
- 92532-01 Serial Loop Back Device
- 03H99-01 CD 3700 SL Needle
- 03H96-01 Solenoid Ring Pull
- 95519-01 Data Station Cable
- 03H98-02 Waste Bottle Cable

Sample Loader Accessories Kit

04H84-04 Sample Loader Racks

Optional Accessories

- 25860-01 Bar Code Label Dispenser
- 99650-01 Bar Code Tube ID Labels
- 99652-01 QC Bar Code Labels
- 04H34-01 Syringe, 10 mL
- 28561-01 Syringe, 2.5 mL
- 28560-01 Syringe, 500 µL
- 03H99-01 Needle, Vent/Aspiration
- 03H76-01 CELL-DYN 3700 Shear Valve Center Section
- 99624-01 Pre-Printed Tickets

*Orderable by Abbott personnel only



CELL-DYN Ruby

Hardware

- 07H40-02 Bar Code Reader, Hand-Held, Trigger Activated
- 05H00-02 Display, Flat Panel
- 07H96-01 Keyboard
- 09H41-01 Mouse
- 08H07-01 Printer, Graphics (color laser with USB port connector)
- 08H73-16 Printer, Graphics (Color desktop)
- 08H60-05 OKI B4600 220V Printer Mono Laser Printer

Accessories Kit List Number 09H04-01

- 8952087701* Cable, Data Station (HSSL)
- 09H00-01 Cable, (printer), 10'
- 8240051601* Cable, Power, 6'7"
- 06H92-01 Diluent/Sheath Filter
- 09H06-01 Needle, SL
- 21704-01 Plug, Dummy Waste
- 03H96-01 Ring, Pull Solenoids
- 92532-01 Serial Loop-Back Device (RS232)
- 09H38-02 Tubing, Reagent WBC Lyse
- 09H41-01 Mouse, Digital USB
- 07H40-02 Bar Code Reader, Handheld, Trigger Activated
- 08H43-01 Tubing, Diluent/Sheath
- 08H41-01 Tubing, HB Lyse
- 02H96-01 Tubing, Waste Outlet

Optional Accessories

- 07H67-02 Cap (large), Reagent line tubing
- 99650-01 Labels
- 99652-01 Labels, Bar Code, Q-Labels
- 09H31-02 Labels, Bar Code, Background
- 06H62-01 Labels, CELL-DYN Rack Bar Code, set of 100
- 06H64-01 CELL-DYN Shear Valve Center Section
- 04H34-01 Syringe, 10 mL
- 28561-01 Syringe, 2.5 mL
- 04H40-01 Syringe Kit, 2.5 mL
- 28560-01 Syringe, 500 µL
- 08H06-01 Kit Rack, Autoloader
- 09H32-01 Open Mode Probe
- 91485-01 Tubing Set, Transfer Pump
- 09H57-01 CDR FAN FLTR ASSY (80mm RIGHT SIDE)
- 03H86-01 Check Valve

*Orderable by Abbott personnel only

CELL-DYN Emerald

Accessories

- 09H62-01 Bar Code Scanner
- 09H68-01 Emerald Grease (3gm)
- 09H54-02 European Power Cord
- 09H54-04 Flat Screwdriver/Key
- 09H50-01 Diluent Reagent line withcap
- 09H51-01 Waste line with cap

Consumables

- 03B96-02 Printer paper 8.5 x 11" sheets
- 99630-01 Bar Code Labels, Tube ID 1000 labels per roll

CELL-DYN Sapphire

Hardware

- 08H01-05 CELL-DYN Sapphire Data Station Computer
- 07H40-02 Bar Code Reader, Hand-Held, Trigger Activated
- 08H02-01 Display, Flat Panel 17 inch
- 08H02-04 Display, Flat Panel 19 inch
- 08H14-01 Keyboard Standard - (Flex style), English
- 07H96-02 Keyboard Standard, English
- 01H08-01 Mouse Pointing Device
- 08H07-08 Printer, Graphics (color laser with USB port connector) 110 VAC
- 20825-01 1 Printer, Ticket (with parallel port connector) 110 VAC
- 20826-01 1 Printer, Ticket (with parallel port connector) 220 VAC

Accessories Kit (List Number 08H03-01)

- 54305-01 Brush, Impedance Aperture Made of Camel Hair
- 08H08-01 Cable, Data, Analyzer to Data Station
- 08H54-01 Cable, Data, Test Interface
- 08H53-04 Vent Assembly
- 02H63-02 Probe, Sample Aspiration, Nitinol
- 92532-01 Serial Loop Back Connector
- 02H88-01 Tubing set, Reagent Inlet and Waste Outlet
- 02H88-02 Tubing set, Reagent Inlet and Waste Outlet
- 91485-01 Tubing set, Sample Transfer Pump
- 21704-01 Waste Sensor Plug

Optional Accessories

- 09H00-01 Cable, USB Printer
- 07H67-01 Cap, small, Reagent line tubing
- 07H67-02 Cap, large, Reagent line tubing
- 99650-01 Labels, Bar Code, Tube ID
- 99651-01 Labels, Bar Code, Tube ID
- 99652-01 Labels, Bar Code, Q-Labels
- 01H59-01 Labels, Bar Code, Q-Labels
- 06H62-01 Labels, Bar Code, Rack
- 08H06-01 Rack, Autoloader
- 08H06-02 Rack, Autoloader
- 08H06-04 Rack, Autoloader (Pedia Rack 1)
- 08H06-06 Rack, Autoloader (Pedia Rack 2)
- 09F99-01 Rack Completion Indicators
- 08H13-01 Syringe, Diluent/Sheath, 10mL
- 08H49-04 Syringe, Diluent/Sheath, 5mL
- 08H46-01 Syringe, Impedance Injection/Metering, 100µL
- 08H48-01 Syringe, Reticulocyte Reagent and WBC Reagent - Part A, 2.5mL
- 08H47-01 Syringe, Optical Injection/Metering, 500µL
- 08H45-01 Syringe, WBC Reagent - Part B, 250µL
- 02H90-01 Tubing, Reagent Diluent/Sheath (Red-striped)
- 02H90-02 Tubing, Reagent Diluent/Sheath (clear, no stripes)
- 02H91-01 Tubing, Reagent, Hemoglobin
- 02H89-01 Tubing, Reagent, WBC - Part A
- 02H99-01 Tubing, Reagent, WBC - Part B
- 02H96-01 Tubing, Waste Outlet



ARCHITECT Systems

Accessory kit 1 (c4000) - LN 02P68-01

- Installation components**
- 10 Micron Filter, Water Bath
- High Concentration Waste Tubing Kit
- ICT O-Ring, Probe, and Probe Holder
- Large Cartridge Segment, Inner 02P80-01
- Large Cartridge Segment, Outer (Target) 02P83-01
- Large Cartridge Segment, Outer 02P84-01
- Small Cartridge Segment, Inner 02P79-01
- Small Cartridge Segment, Outer 02P81-01
- Small Cartridge Segment, Inner (Target) 02P82-01
- Reagent Probe 01G47-03
- Reagent Probe Tubing 02P76-01
- Sample Probe 01G48-04
- Sample Probe Tubing 02P77-01
- Sample Wash Solution Carrier 02P78-01
- Waste and Water Tubing Kit**
- Maintenance components**
- 10 mm Wrench
- Container, Parts Case
- Cuvette Segment Alignment Tool 02P86-01
- Nozzle, Cleaning Wire 09D50-02
- Phillips Screwdriver
- Slotted Screwdriver
- Spare components**
- 1 mL Syringe 09D41-02
- 20 mL reagent Cartridge Adaptor 09D22-12
- Cuvette Dry Tip 09D51-02
- Cuvette Pair Replacement Set 01G46-02
- ICT Probe 09D63-03
- ICT Probe Holder
- Mixer 09D59-02
- Probe Screw, Sampler/ Reagent
- Reagent Probe 01G47-03
- Reagent Probe Tubing, c4000 02P76-01
- Reagent Syringe O-ring 09D53-02
- Reagent Syringe Seal Tip # 1 09D39-02
- Reagent Syringe Seal Tip # 2 09D40-02
- Sample Probe 01G48-04
- Sample Probe Tubing, c4000 02P77-01
- Sample Wash Solution Syringe O-ring 09D52-02
- Sample Wash Solution Syringe Seal Tip # 1 09D37-02
- Sample Wash Solution Syringe Seal Tip # 2 09D38-02
- Source Lamp 09D45-02
- Accessory kit 2 (c4000) - LN 02P73-01**
- Carrier Calibration Tool 01P76-01
- Pressure Monitor PCB
- Sample Carriers
- SH Bar code Tool 06E69-01

Customer maintenance kit (c4000) - LN 02P69-01
 1 mL Syringe 09D41-02
 ICT Reference Solution Check Valve 09D35-02
 Reagent Syringe O-ring 09D53-02
 Reagent Syringe Seal Tip # 1 09D39-02
 Reagent Syringe Seal Tip # 2 09D40-02
 Sample/Wash Solution Syringe O-ring 109D52-02
 Sample/Wash Solution Syringe Seal Tip #1 09D37-02
 Sample/Wash Solution Syringe Seal Tip #2 109D38-02
 Source Lamp 09D45-02

Accessory kit 1 (c8000) - LN 01G09-02

Installation components
 Power Cable - UL and IEC Plug 02J54-01
 Waste and Water Tubing Kit
 High Concentration Waste Tubing Kit

ICT Probe 09D63-03
 ICT Probe Holder
 Reagent Probe 01G47-03
 Reagent Probe Tubing 01G47-02
 Sample Probe 01G48-04
 Sample Probe Tubing 01G48-02
 c8000 (R1)/c16000 (R1 and R2) Large Cartridge, Segment A (Target) 04J30-01
 c8000 (R1)/c16000 (R1 and R2) Small Cartridge, Segment A, B, C 01G51-01
 c8000 (R1)/c16000 (R1 and R2) Segment D (Target) 04J32-01
 R2, Small Cartridge, Segment A (Target) 04J29-01
 R2, Large Cartridge, Segment B, C, and D 04J31-01
 R2, Small Cartridge, Segment B, C, and D 01G52-01

Maintenance components

Phillips Screwdriver
 Slotted Screwdriver
 10 mm Wrench
 c8000 Cuvette Segment Alignment Tool 02J93-01
 Nozzle-Cleaning Wire 09D50-02
 Container, Parts case

Accessories

20 mL Reagent Cartridge Adapter 09D22 (-11 or-12)
 Small Reagent Cartridge Adapter 09D22-07

Spare components

1 mL Syringe 09D41-02
 Cuvette Dry Tip 09D51-02
 Cuvette Pair Replacement Set 01G46-02
 ICT O-ring 09F93-02
 Mixer 09D59-02

Reagent Probe 01G47-03

Tubing 01G47-02
 Reagent Syringe O-ring 09D53-02
 Reagent Syringe Seal Tip # 1 09D39-02
 Reagent Syringe Seal Tip # 2 09D40-02
 Reagent/Sample Probe Screw 02J51-01
 Sample Probe 01G48-04
 Sample Probe Tubing 01G48-02
 Sample/Wash Solution Syringe O-ring 09D52-02
 Sample/Wash Solution Syringe Seal Tip #1 09D37-02
 Sample/Wash Solution Syringe Seal Tip #2 09D38-02
 Source Lamp 09D45-02



Customer maintenance kit (c8000) - LN 02J53-01
 1 mL Syringe 209D41-02
 ICT Reference Solution Check Valve 09D35-02
 Reagent Syringe O-ring 09D53-02
 Reagent Syringe Seal Tip # 1 09D39-02
 Reagent Syringe Seal Tip # 2 09D40-02
 Sample/Wash Solution Syringe O-ring 09D52-02
 Sample/Wash Solution Syringe Seal Tip #1 09D37-02
 Sample/Wash Solution Syringe Seal Tip #2 09D38-02
 Source Lamp 09D45-02

Accessory kit 1 (c16000) - LN 08L71-02

Installation components
 Power Cable - UL and IEC Plug 02J54-01
 Waste and Water Tubing Kit
 High Concentration Waste Tubing Kit
 ICT Probe 09D63-03
 ICT Probe Holder

Reagent Probe - R1A/R2B (L) 09D48-02
 Reagent Probe - R1B/R2A(F) 09D49-02
 Tubing, Joint to R Probe, R1 & 2A09D48-05
 Tubing, Joint to R Probe, R1 & 2B09D49-05
 Sample Probe 01G48-04
 Sample Probe Tubing 01G48-02
 c8000 (R1)/c16000 (R1 and R2) Large Cartridge, Segment A (Target) 04J30-01
 c8000 (R1)/c16000 (R1 and R2) Large Cartridge, Segment A, B, C 01G51-01
 R2, Small Cartridge, Segment A (Target) 04J32-01
 R2, Large Cartridge, Segment B, C, and D 04J31-01
 R2, Small Cartridge, Segment B, C, and D 01G52-01

Maintenance components

Phillips Screwdriver
 Slotted Screwdriver
 10 mm Wrench
 c16000 Cuvette Segment Alignment Tool 08L73-01
 Nozzle-Cleaning Wire 09D50-02
 Container, Parts case

Accessories

20 mL Reagent Cartridge Adapter 09D22 (-11 or-12)
 Small Reagent Cartridge Adapter 09D22-07

Spare components

1 mL Syringe 09D41-02
 Cuvette Dry Tip 09D51-02
 Cuvette Pair Replacement Set 09D33-03
 ICT O-ring 09F93-02
 Peristaltic Pump Tubing Kit
 Mixer 09D59-02

Pipettor Arm Cover Screw 09D46-20

Reagent Probe R1A/R2B 09D48-02
 Reagent Probe R1B/R2A 09D49-02
 Reagent Probe Screw 09D48-10
 Tubing, Joint to R Probe, R1 & 2A 09D48-05
 Tubing, Joint to R Probe, R1 & 2B 09D49-05
 Reagent Syringe O-ring 09D53-02
 Reagent Syringe Seal Tip # 1 09D39-02
 Reagent Syringe Seal Tip # 2 09D40-02
 Sample Probe 01G48-04
 Sample Probe Tubing 01G48-02
 Probe Screw: c8000 (Reagent and Sample)/c16000 (Sample) 02J51-01
 Sample/Wash Solution Syringe O-ring 09D52-02
 Sample/Wash Solution Syringe Seal Tip #1 09D37-02
 Sample/Wash Solution Syringe Seal Tip #2 09D38-02
 Source Lamp 09D45-02

ARCHITECT i System accessory kits - LN 08C94-01 (i2000), LN 03M77-01 (i2000SR), and LN 01L87-01(i1000SR)

Customer maintenance kit (c16000) - LN 08L72-01
1 mL Syringe 09D41-02
ICT Reference Solution Check Valve 09D35-02
Reagent Syringe O-ring 09D53-02
Reagent Syringe Seal Tip #1 09D39-02
Reagent Syringe Seal Tip #2 08D46-02
Sample/Wash Solution Syringe O-ring 09D52-02
Sample/Wash Solution Syringe Seal Tip #1 09D37-02
Sample/Wash Solution Syringe Seal Tip #2 09D38-02
Source Lamp 09D45-02

i2000 and i2000SR components - LN 08C94-01 and LN 03M77-01
Bag, Biohazard
External Waste Tubing
Filter, Card Cage/Supply 08C94-07
Filter, Processing Center 08C94-14
Inlet assembly, buffer Maintenance Kit
• Bar Code Calibration Tool 06E67-01
• Carrier Calibration Tool 05E13-01
• Flashlight
• Fuse Kit
• Grease
• Lens Paper
• Maintenance Cleaning Bottle 02G16-99
• Optics Cap
• WZ Probe Maintenance Water Bottle 06E68-01
• Screwdriver #1 Phillips
• Screwdriver #2 Phillips
• SH Bar Code Tool 06E69-01
• Thermistor Removal Wrench
• Valve Removal Tool
Power cord kit
Probe, Wash Zone 08C94-35
Probe (Sample/Reagent) 08C94-42
Probe/Tubing, Waste Arm 08C94-80
Sensor, Level, Buffer 08C94-25
Sensor, Level, Trigger 08C94-26
Sensor, Level, Pre-Trigger 08C94-27
Tubing/Sensor, Temp, WZ 08C94-87
Tubing, Wash Buffer Transfer 08C94-21
Wash Buffer Preparation Container 08C94-56
Wash Buffer Reservoir

i2000 components - LN 08C94-01
Internal component cover 1 06E27-10
Internal component cover 2 & 3 06E27-20
Internal component cover 4 (i2000 accessory kit only) 06E27-30
Internal component cover 5 (i2000 accessory kit only) 06E27-40
Internal component cover 6 (i2000 accessory kit only) 06E27-50
Internal component cover 7 (i2000 accessory kit only) 06E27-60
Internal component cover 8 (i2000 accessory kit only) 06E27-70
i2000SR components - LN 03M77-01
STAT Probe Tubing (i2000SR accessory kit only) 03M77-49
Internal component cover 1 06E27-11
Internal component cover 2 & 3 06E27-21
Internal component cover 4 (i2000SR accessory kit only) 02J63-14
Internal component cover 5 (i2000SR accessory kit only) 02J63-15
Internal component cover 6 (i2000SR accessory kit only) 02J63-16
Internal component cover 7 (i2000SR accessory kit only) 02J63-17



ARCHITECT 11000SR components - LN 01L87-01

- Bag, Biohazard
- Bleach Preparation Container 08C94-83
- Buffer filter 08C94-29
- Buffer outlet assembly 01P12-01
- Card cage/SCC door filter 03L99-01
- Card cage filter 06L00-01
- External Waste Tubing
- Internal Decon Extension Tubing/Cable Kit 01P83-01
- Maintenance Kit:
 - Bar Code Calibration Tool 06E67-01
 - Buffer Reservoir Cap
 - Carrier Calibration Tool 01P16-01
 - Flashlight
 - Fuse Kit
 - Lens Paper
- Maintenance Cleaning Bottle 02G16-99
- Optics Cap
- WZ Probe Maintenance Water Bottle 06E68-01
- Screwdriver #1 Phillips
- Screwdriver #2 Phillips
- SH Bar Code Tool 06E69-01
- Thermistor Removal Wrench
- Valve Removal Tool
- Ground strap
- O-ring Removal Tool Probe (Sampler/Reagent) 06C94-42
- Probe, Wash Zone 08C94-35
- Reagent Carriers
- Sample Carriers
- Sensor, Level, Buffer 06L01-01
- Sensor, Level, Pre-Trigger 8C94-27
- Sensor, Level, Trigger 8C94-26
- Tubing, Probe 06L04-01
- Tubing, Sensor, Temp, WZ 06C94-87
- Tubing, Wash Buffer Transfer 08C94-21
- Unloader
- Wash Cup Baffle 01P41-01
- Wash Buffer Preparation Container 08C94-56
- Wash Buffer Reservoir 06L06-01
- Waste pressure switch to floor tubing
- Additional accessories
 - Alternate c8000/c16000 Reagent Supply Center Segments:
 - c8000 (R1)/c16000 (R1 and R2) Large Cartridge, Segment A, B, C 04J33-01
 - R2, large cartridge, segments B, C, and D 04J31-01
 - R2, small cartridge, segments B, C, and D 01G52-01
 - Alternate c4000 Reagent Supply Center Segments:
 - Large Cartridge Segment, Inner 02P80-01
 - Large Cartridge Segment, Outer 02P84-01
 - Large Cartridge Segment, Outer (Target) 02P83-01
 - Small Cartridge Segment, Inner 02P79-01
 - Small Cartridge Segment, Outer 02P81-01
 - Small Cartridge Segment, Inner (Target) 02P82-01
 - ARCHITECT ARM (Automated Reconstitution Module), accessory 08C95-89
 - Cuvette Segment (c4000) 02P75-01
 - Cuvette Segment (c8000) 01G46-01
 - Cuvette Segment (c16000) 09D32-05
 - External Waste Pump:
 - i2000/i2000SR 08C94-19
 - c System 09D61-03
 - High Concentration Waste Bottle 03E50-26
 - High Concentration Float Switch Cable 03E50-31
 - LAS Sample Carousel ID Labels (i2000) sheet 08C96-25



MEDICA

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

AUTHORIZATION LETTER

TO WHOM IT MAY CONCERN:

MEDICA CORPORATION, having facilities at 5 Oak Park Drive, Bedford, MA 01730, USA, do hereby authorize the company:

GBG-MLD SRL
65 Tighina Site
Office 607
Chisinau, MD-2001
Republic of Moldova

to be our **DISTRIBUTOR** for the **EasyLyte®**, **EasyElectrolytes™**, **EasyBloodGas™** and **EasyStat®** analyzers as well as associated reagents and consumables in **Moldova**.

GBG-MLD SRL is authorized by MEDICA CORPORATION to enter tenders and quote for all aforementioned products.

GBG-MLD SRL is authorized by MEDICA CORPORATION to present offers on our behalf to tenders placed by the government and other institutions for Medica products and consumables

GBG-MLD SRL responsibilities include sales of the **EasyLyte®**, **EasyElectrolytes™**, **EasyBloodGas™** and **EasyStat®** analyzers and providing service as well as maintaining a supply of reagents and replacement parts.

GBG-MLD SRL is also authorized to provide warranty service for the Medica **EasyLyte®**, **EasyElectrolytes™**, **EasyBloodGas™** and **EasyStat®** analyzers.

This authorization is effective immediately and is valid until December 31, 2022, unless revoked earlier in writing by Medica Corporation.


David Hagopian
VP, Sales & Marketing
MEDICA CORPORATION

2/4/2022
Date



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



Calin Moldovean

President

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



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.





Medica Corporation
5 Oak Park Drive
Bedford, Massachusetts 01730
Tel: 781.275.4892
Fax: 781.275.2731
www.mediacorp.com

Declaration of Conformity


Product Name:

EasyLyte and accessories per attachment


Model/Type:

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

Manufacturer

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

Representative

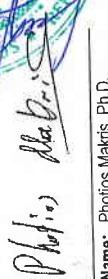
 EBC REP
Energio Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

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: Phoivos 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 Solutions 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



EasyElectrolytes Accessories

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

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code	EDMA Code
2104	EasyLyte Tubing Kit	21 07 11 02	21 07 11 02
2100	EasyLyte Calcium Tubing Kit	21 07 11 02	21 07 11 02
2492	EasyLyte Internal Filling Solution (125ml)	11 04 04 90	11 04 04 90
2309	EasyLyte Wash Solution (50ml)	11 04 04 90	11 04 04 90
2111	EasyLyte Urine Diluent (500ml)	11 04 04 90	11 04 04 90
2577	EasyLyte Standard Solution, Urine (50ml)	11 04 04 90	11 04 04 90
2323	EasyLyte Probe Wipers (6)	21 07 11 02	21 07 11 02
2541	EasyLyte Printer Paper (9 rolls)	21 07 11 02	21 07 11 02
2595	EasyLyte EasySampler Sample Cups, 500ul (500)	21 07 11 02	21 07 11 02
2596	EasyLyte Sample Cups 2.0mL (500)	21 07 11 02	21 07 11 02
10745	Anti-Evaporation Caps (500)	21 07 11 02	21 07 11 02
2293	EasyLyte Capillary Tubes	21 07 11 02	21 07 11 02
2598	EasyLyte Capillary Adaptor Kit	21 07 11 02	21 07 11 02
2292	EasyLyte Capillary Adaptor Cleaning Kit	21 07 11 02	21 07 11 02
2578	EasyLyte Red Dye Test Solution (50ml)	11 30 01 11	11 30 01 11
2572	EasyLyte Troubleshooting Kit	21 07 11 02	21 07 11 02
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 07 11 02	21 07 11 02
2105	EasyLyte Quarterly Operating Kit	21 07 11 02	21 07 11 02
2095	EasyLyte Maintenance Kit	21 07 11 02	21 07 11 02
2076	EasyLyte Sample Tray	21 07 11 02	21 07 11 02
2074	EasyLyte Sample Cup Retainer Ring	21 07 11 02	21 07 11 02
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 07 11 02	21 07 11 02
2934	EasyLyte Barcode Reader Kit	21 07 11 02	21 07 11 02





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 : Flexor XL
Catalog No. : 6002-700
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

Code: 6002-700

Doc. no: 510

Version: 06





Declaration of Conformity



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.

Code: 6002-700

Doc. no.: 510

Version: 06





Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 02 16316 019

Manufacturer:

BOWA-electronic GmbH & Co. KG

Heinrich-Hertz-Strasse 4-10

72810 Gomaringen

GERMANY

Facility(ies):

BOWA-electronic GmbH & Co. KG

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

Product

Category(ies):

**Electrosurgical Unit and accessories
Argon Coagulation Unit and accessories
Electrode handles
Active electrodes and instruments
monopolar and bipolar forceps
endoscopic and laparoscopic instruments
instruments for vessel sealing
neutral electrodes
bipolar scissors**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report-No.: 713102471

Valid from: 2017-03-09

Valid until: 2022-03-08

Date, 2017-03-08

Stefan Preis



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 1

TÜV SÜD Product Service GmbH - Zertifizierungsstelle - Rullerstraße 65 - 80339 München - Germany

Zertifizierungsvertrag

Grundlage für die Zertifizierungsleistung ist die Prüf- und Zertifizierungsordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierungsordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifizierungssystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:

- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben
- und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.

On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuev-sued.de/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:

- Validity of the quoted test standard(s) in addition for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

Abkürzungen / Benennungen
Accreditations / notifications
(Stand: 14.10.2017)
(as of 2017-10-14)

Deutschland / Germany

Produktsicherheitsgesetz (ProdSG) /
Product Safety Act (ProdSG)

Europa / Europe

- Niederspannungsrichtlinie 2006/95/EG
- Spielzeugrichtlinie 2009/48/EG
- Richtlinie für aktive medizinische Implantate 90/269/EEG
- Richtlinie für Medizinprodukte 93/42/EEG
- Richtlinie für in-vitro-Diagnostika 98/76/EG
- Richtlinie für Gasverbrauchseinrichtungen 2009/142/EG
- Richtlinie für persönliche Schutzausrüstungen 89/686/EEG
- EMV-Richtlinie 2004/78/EG
- Richtlinie für Sportboote 94/25/EG + 2003/44/EG
- Richtlinie für Maschinen 2006/42/EG
- Richtlinie für Ex-Schutz Geräte 94/9/EG
- Low Voltage Directive 2006/95/EC
- Toys Directive 2009/48/EC
- Directive for Active Implantable Medical Devices 90/269/EEC
- Directive for Medical Devices 93/42/EEC
- Directive on In Vitro Diagnostic Medical Devices 98/76/EC
- Directive for Gas Appliances 2009/142/EC
- Directive for Personal Protective Equipment 89/686/EEC
- EMC Directive 2004/78/EC
- Directive for Recreational Craft 94/25/EC + 2003/44/EC
- Directive for Machinery 2006/42/EC
- Directive for Ex Safe Equipment 94/9/EC
- ENEC Agreement for luminaires, household and IT equipment

USA

- Nationally Recognized Testing Laboratory (NRTL) to 29 CFR 1910.7 by OSHA
- Accredited for FDA 510(k) Third Party Review
- Conformity Assessment Body to the MRA for Medical Devices; FDA QSRReg Inspections, FDA 510(k) Third Party Review

Asien-Pazifik Region / Asia Pacific

- Recognized Certification Body to Electrical Products (Safety) Regulation; Hong Kong
- Konformitätsbewertungsstelle / Conformity Assessment Body to the MRA for Medical Devices; Australien / Australia
- Konformitätsbewertungsstelle / Conformity Assessment Body to the MRA for Medical Devices; Neuseeland / New Zealand

Weltweit / Worldwide

- NCB im CB-Schema des IECEE / NCB in the CB Scheme of IECEE
- EXCB in the IECEE Scheme of IECEE
- Zertifizierungsstellen durch DAKS akkreditiert
- DE-ZE-11321-01, DE-ZM-11321-09 und DE-ZM-11321-04
- Certification Bodies accredited by DAKS
- DE-ZE-11321-01, DE-ZM-11321-09 and DE-ZM-11321-04

Zertifizierungsstelle für Produkte - e-mail: ps@tuev-sued.de
Zertifizierungsstelle für Medizinprodukte - e-mail: mtd@tuev-sued.de
Kundenservice / Clients Service - Phone: +49 89 9595 08-42 30 - e-mail: ps-a@tuev-sued.de





Deutsche
Akkreditierungsstelle
D-20113-1321-01-00



Product Service

Zertifikat

Nr. Q5 016316 0021 Rev. 00

Zertifikatsinhaber:

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomarlingen
DEUTSCHLAND

Zertifizierungs-
zeichen:



Geltungsbereich:

Design und Entwicklung, Produktion und Vertrieb von nicht-sterilen Medizinprodukten:

- Elektrochirurgiegegeräten und Zubehör,
- Argon-Koagulationsgeräten und Zubehör,
- Elektrochirurgischen Handgriffen,
- Aktiven Elektroden und Instrumenten,
- Monopolaren und bipolaren Pinzetten,
- Endoskopischen und laparoskopischen Instrumenten,
- Instrumenten zur Gefäßversiegelung,
- Neutraielektroden,
- Bipolaren Scheren

Die Zertifizierstelle von TÜV SÜD Product Service GmbH bescheinigt, dass das oben genannte Unternehmen ein Qualitätsmanagementsystem eingeführt hat und anwendet, das den Anforderungen der genannten Norm(en) entspricht. Umseitige Hinweise sind zu beachten.

Bericht Nr.:

713195510

Gültig ab:

2019-06-05

Gültig bis:

2022-02-28

Datum:

2019-06-05

S. Puvrit

Stefan Preis
Head of Certification/Notified Body



Seite 1 von 2

TÜV SÜD Product Service GmbH • Zertifizierstelle • Ridlerstraße 65 • 80339 München • Deutschland



Deutsche
Akkreditierungsstelle
D-20113-1321-01-00

Zertifikat

Nr. Q5 016316 0021 Rev. 00

Angewandte
Norm(en):

EN ISO 13485:2016
Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke (ISO 13485:2016)
DIN EN ISO 13485:2016

Betriebsstätte(n):

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10, 72810 Gomarlingen, DEUTSCHLAND
BOWA Polska Sp. z o. o.
Zielkowo, ul. Obornicka 10, 60-002 Suchy Las, POLEN

Seite 2 von 2

TÜV SÜD Product Service GmbH • Zertifizierstelle • Ridlerstraße 65 • 80339 München • Deutschland

