EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1023580-1

Manufacturer: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

Digitally signed by Iarovoi Petru
Date: 2022.11.11 19:20:09 EET
Reason: MoldSign Signature
Location: Moldova

Products:
- Analgetic control kits
- Angiographic accessories kits
- Aspiration catheters
- Balloon catheters
- Biliary prosthesis, catheters and kits
- Catheters and kits for dialysis
- Catheters for oxygen rhinoscopic administration
- Central venous pressure measuring kits
- Connectors
- Cystostomy catheters and kits
- Dilating catheters and dilators
- Drainage catheters and kits
- Drains
- Embolectomy and thrombectomy catheters
- Embolization catheters

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 84949468-50

Effective date: 2021-05-12

Expiry date: 2024-05-26

Issue date: 2021-05-12

TÜV Rheinland LGA Products GmbH Eingestellt

Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1023580-1

Manufacturer: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

- Extenders
- Feeding catheters
- Flat antibacterial filters
- Guide wires
- Gynecology catheters and kits
- Insemination catheters
- Introducers
- Kits for stent introduction
- Nephrostomy catheters and kits
- Pediatric catheters
- Puncture kits
- Rotating Y type adapters with and without valve
- Scalpels
- Stopcock manifolds and stopcocks
- Syringes
- Thermodilution kits
- Thrombolysis catheters and kits
- Treatment needles
- Ureteral catheters
- Urological catheters
- Vessel compression tourniquets
- Vessel irrigation catheters

Report No.: 84949468-50

Effective date: 2021-05-12

Expiry date: 2024-05-26

Issue date: 2021-05-12

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1023580-1

Manufacturer:
BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

- Vessel slings
- Sets for venous insufficiency treatment
- Infusion microcatheters
- Support catheters

For the following medical devices, the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Aspirators
- Blockers
- Bottles, containers for aspiration
- Dilatation catheters for salivary duct
- Endoscopic balloon dilation catheters
- Guide wire grips
- Guide wire introduction tubes
- Insemination catheter universal luer lock caps
- Larynx anesthesia catheters
- Luer lock caps
- Mandrins
- Pushers
- Redon plugs

Report No.: 84949468-50

Effective date: 2021-05-12

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Issue date: 2021-05-12

TÜV Rheinland LGA Products GmbH Prüfstelle

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EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1023580-1

Manufacturer: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

- Radial artery compression tourniquet kits
- Stents for salivary ducts
- Suction connectors
- Universal hubs luer lock

Replaces EC Certificate, Registration No.: HD 60144654 0001

Report No.: 84949468-50

Effective date: 2021-05-12

Expiry date: 2024-05-26

Issue date: 2021-05-12

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1023580-1

Manufacturer: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	BALTON Sp. z o.o. ul. Nowy Świat 7/14 00-496 Warszawa Poland	Activity: Administration.
/02	BALTON Sp. z o.o. ul. Modlińska 294 03-152 Warszawa Poland	Activity: Design and development, production and distribution of sterile, disposable medical devices for dialysis and hemodialysis, radiology, cardiology, urology, anesthesiology, gynecology and general surgery.
/03	BALTON Sp. z o.o. ul. Strzelnicza 3 18-300 Zambrów Poland	Activity: Production of disposable medical devices.
/04	BALTON Sp. z o.o. ul. Topolowa 23 05-119 Łajski Poland	Activity: Production of components and packaging materials for disposable medical devices and EO gas sterilization service according to EN ISO 11135:2014 standard.

Report No.: 84949468-50

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Issue date: 2021-05-12

TÜV Rheinland LGA Products GmbH

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

BALTON sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date March 15, 2024

Notified Body Confirmation Letter
Reference : 61031/2024

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

BALTON sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland
SRN Number: PL-MF-000010568

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland
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The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

AUDIT_CERT_REVIEW
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
URETERAL CATHETER: **URETERAL CATHETER Tiemann type** **URETERAL CATHETER Olive type** **URETERAL CATHETER Couvelaire type** **URETERAL CATHETER Chevassu type** **URETERAL CATHETER Nelaton type** **Basic UDI-DI: 5901297URETERALKF**	Class IIa	Ureteral catheter	HD 1023580-1 NB 0197
URETERAL STENTING KIT **Basic UDI-DI: 5901297STINTODUCTIONYB**	Class IIa	Kit for stent introduction	HD 1023580-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
CYSTOSTOMY KIT **Basic UDI-DI: 5901297CYSTOSTOMYY5**	Class IIa	Cystostomy catheter and kit	HD 1023580-1 NB 0197
KIT FOR NEPHROSTOMY CATHETER EXCHANGE **Basic UDI-DI: 5901297NEPHROSTOMYDM**	Class IIa	Kit for catheters exchange	HD 1023580-1 NB 0197
HIGH PRESSURE STOPCOCK: **HIGH PRESSURE STOPCOCK Three-way type** **HIGH PRESSURE STOPCOCK One-way type** **Basic UDI-DI: 5901297KVUL**	Class IIa	Stopcock manifolds and Stopcocks	HD 1023580-1 NB 0197
PERCUTANEOUS DRAINAGE KIT: **PERCUTANEOUS DRAINAGE KIT** **One-step method** **PERCUTANEOUS DRAINAGE KIT** **Two-step method** **Basic UDI-DI: 5901297DRAINAGEPERCUTAN7M**	Class IIa	One-step method drainage catheter and kit Two-step method drainage kit	HD 1023580-1 NB 0197
HYSTEROSALPINGOGRAPHY CATHETER **Basic UDI-DI: 5901297GYNECOLOGYG9**	Class I devices placed on the market in sterile condition	Hysterosalpingography catheter and kit	HD 1023580-1 NB 0197
INTRODUCER WITH PEEL-APART SHEATH KIT **Basic UDI-DI: 5901297ZWERK8Q**	Class III	Kit to introduce electrodes with split sheath	HD 1023580-1 NB 0197
VENTRAL DRAIN **Basic UDI-DI: 5901297VENTRALDRAINSHW**	Class IIa	Ventral drain	HD 1023580-1 NB 0197
SET FOR VENOUS INSUFFICIENCY TREATMENT, FLEBOGRIF	Class IIa	Set for venous insufficiency treatment - FLEBOGRIF	HD 1023580-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 5901297PHLEBOLOGYAL			
ANGIOGRAPHIC NEEDLE **Basic UDI-DI: 5901297IADE2**	Class IIa	Angiographic needles	HD 1023580-1 NB 0197
ASPIRATION CATHETER REDON TYPE **Basic UDI-DI: 5901297KORGJ**	Class IIa	REDON type aspiration catheter	HD 1023580-1 NB 0197
POLYMER GUIDEWIRE WITH HYDROPHILIC COATING, ENTER: **POLYMER GUIDEWIRE WITH HYDROPHILIC COATING, ENTER** **Straight type, floppy** **POLYMER GUIDEWIRE WITH HYDROPHILIC COATING, ENTER** **Straight type, medium stiff** **POLYMER GUIDEWIRE WITH HYDROPHILIC COATING, ENTER** **Straight type, stiff** **POLYMER GUIDEWIRE WITH HYDROPHILIC COATING, ENTER** **Angled type, floppy** **POLYMER GUIDEWIRE WITH HYDROPHILIC COATING, ENTER** **Angled type, medium stiff** **POLYMER GUIDEWIRE WITH HYDROPHILIC COATING, ENTER** **Angled type, stiff** **Basic UDI-DI: 5901297PPNH6**	Class IIa	Polymer guide wire with hydrophilic coating ENTER	HD 1023580-1 NB 0197
EMBOLECTOMY AND THROMBECTOMY CATHETER: **EMBOLECTOMY AND THROMBECTOMY CATHETER** **Single-lumen type**	Class IIa	Embolectomy and trombectomy catheters	HD 1023580-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
EMBOLECTOMY AND THROMBECTOMY CATHETER Double-lumen type **EMBOLECTOMY AND THROMBECTOMY CATHETER Double-lumen for guidewire type** **Basic UDI-DI: 5901297EMBOLECTOMYRE**			
STEEL GUIDEWIRE: **STEEL GUIDEWIRE** **STEEL GUIDEWIRE J type** **STEEL GUIDEWIRE Super stiff type** **STEEL GUIDEWIRE Super stiff J type** **STEEL GUIDEWIRE Super stiff type coated with PTFE** **STEEL GUIDEWIRE Super stiff J type coated with PTFE** **STEEL GUIDEWIRE J type coated with PTFE** **STEEL GUIDEWIRE Coated with PTFE** **Basic UDI-DI: 5901297GUIDEWIRESCP**	Class III	Guide wire	HD 1023580-1 NB 0197
TORQUER **Basic UDI-DI: 5901297TORQUERF4**	Class I devices placed on the market in sterile condition	TORQUER	HD 1023580-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Y CONNECTOR: **Y CONNECTOR** **Stopcock side port type** **Y CONNECTOR** **Luer-lock side port type** **Y CONNECTOR** **Rotating type** **Basic UDI-DI:** **5901297CONNECTORS9B**	Class IIa	Rotating Y type adapter with and without valve	HD 1023580-1 NB 0197
STOPCOCK MANIFOLD: **STOPCOCK MANIFOLD** **Two-way type** **STOPCOCK MANIFOLD** **Three-way type** **Basic UDI-DI: 5901297RAMFZ**	Class IIa	Stopcock manifolds and Stopcocks	HD 1023580-1 NB 0197
URETERAL DOUBLE PIGTAIL CATHETER **Basic UDI-DI: 5901297KMPG8**	Class IIa	Ureteral catheter	HD 1023580-1 NB 0197
NEPHROSTOMY KIT **Basic UDI-DI: 5901297ZNEF8Q**	Class IIa	Nephrostomy catheters and kits	HD 1023580-1 NB 0197
BILIARY PROSTHESIS: **BILIARY PROSTHESIS** **Straight type** **BILIARY PROSTHESIS** **Greenen type** **BILIARY PROSTHESIS** **Pigtail type** **BILIARY PROSTHESIS** **Zimmon type** **Basic UDI-DI:** **5901297BILIARYVQ**	Class IIb excluding Class IIb implantable non-WET	STRAIGHT, GREENEN, PIGTAIL, ZIMMON type prosthesis	HD 1023580-1 NB 0197
DIALYSIS KIT: **DIALYSIS KIT**	Class IIb excluding Class IIb	Catheters and kits for dialysis	HD 1023580-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Single-lumen type **DIALYSIS KIT** **Single-lumen type Y** **DIALYSIS KIT** **Single-lumen straight type** **DIALYSIS KIT** **Double-lumen type** **DIALYSIS KIT** **Triple-lumen type** **Basic UDI-DI:** **5901297DIALYSIS5W**	implantable non-WET		
INTRODUCER KIT **Basic UDI-DI:** **5901297INTRODUCERSF7**	Class III	Introducer; Introducer for Cardiology; Radial Artery Introducer for Cardiology; Long Introducer; Braided Introducer	HD 1023580-1 NB 0197
SIROLIMUS ELUTING COBALT-CHROMIUM CORONARY STENT, ALEX **Rapid Exchange delivery system type** **SIROLIMUS ELUTING COBALT-CHROMIUM CORONARY STENT, ALEX PLUS** **Rapid Exchange delivery system type** **Basic UDI-DI: 5901297ALEX43**	Class III	Cobalt-Chromium Sirolimus Eluting Coronary Stent ALEX with Delivery System, Rapid Exchange Sirolimus Eluting Cobalt-Chromium Coronary Stent with Delivery System, Rapid Exchange, ALEX PLUS	EC Certificate: 145099-21-03-25 EC Design Certificate: 145100-21-03-25 NB 2409 EC Certificate: 145016-20-07-21 EC Design Certificate: 145017-20-07-21 NB 2409
Anaesthesia Sets: **EPIDURAL ANAESTHESIA SET** **Small type** **EPIDURAL ANAESTHESIA SET**	Class III	Anaesthesia Sets	EC Certificate: 145084-21-03-25 EC Design Certificate:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Extended type **Basic UDI-DI: 5901297ANAESTHESIASETSYK**			145085-21-03-25 NB 2409
SIROLIMUS ELUTING COBALT-CHROMIUM CORONARY BIFURCATION STENT, BIOSS LIM C **Rapid Exchange delivery system type** **Basic UDI-DI: 5901297BIOSSLIMCP2**	Class III	Sirolimus Eluting Cobalt-Chromium Coronary Bifurcation Stent with Delivery System, Rapid Exchange, BIOSS LIM C	EC Certificate: 145014-20-07-21 EC Design Certificate: 145015-20-07-21 NB 2409
Large Vessel Catheterization Kits: **CENTRAL VENOUS CATHETER KIT** **Single lumen type** **CENTRAL VENOUS CATHETER KIT** **Double lumen type** **CENTRAL VENOUS CATHETER KIT** **Triple lumen type** **CENTRAL VENOUS CATHETER KIT** **Quadruple lumen type** **Basic UDI-DI: 5901297CVCEZ**	Class III	Large Vessel Catheterization Catheters and Kits	EC Certificate: 145081-21-03-25 EC Design Certificate: 145082-21-03-25 NB 2409
SELF-EXPANDING STENT, JAGUAR **Over The Wire delivery system type** **Basic UDI-DI: 5901297JAGUARUY**	Class IIb implantable non-WET	Self-expanding stent with delivery system, JAGUAR	EC Certificate: 145083-21-03-25 NB 2409
Paclitaxel coated peripheral angioplasty balloon catheter, PAK: **PACLITAXEL COATED PERIPHERAL ANGIOPLASTY BALLOON CATHETER, PAK** **Over The Wire delivery system type**	Class III	Paclitaxel coated peripheral angioplasty balloon catheter PAK	EC Certificate: 145091-21-03-25 EC Design Certificate: 145092-21-03-25

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
PACLITAXEL COATED PERIPHERAL ANGIOPLASTY BALLOON CATHETER, PAK Rapid Exchange delivery system type **Basic UDI-DI: 5901297PAKFK**			NB 2409
Peripheral angioplasty catheter LOVIX: **PERIPHERAL ANGIOPLASTY CATHETER, LOVIX Rapid Exchange delivery system type** **PERIPHERAL ANGIOPLASTY CATHETER, LOVIX Over The Wire delivery system type** **Basic UDI-DI: 5901297PBCF6**	Class IIa	Peripheral angioplasty catheter LOVIX	EC Certificate: 145090-21-03-25 NB 2409
CAROTID SELF-EXPANDING STENT, MER Rapid Exchange delivery system type **Basic UDI-DI: 5901297MERFW**	Class III	Carotid self-expanding stent with delivery system, MER RX	EC Certificate: 145071-21-02-08 EC Design Certificate: 145072-21-02-08 NB 2409
COBALT-CHROMIUM PERIPHERAL STENT, NEPTUN C Over the Wire delivery system type **Basic UDI-DI: 5901297NEPTUNC7Q**	Class IIb implantable non-WET	Cobalt-chromium peripheral stents with delivery system, RX/OTW, NEPTUN C	EC Certificate: 145103-21-03-25 NB 2409
COBALT-CHROMIUM STENT FOR RENAL VESSELS, NEFRO C Rapid Exchange delivery system type **Basic UDI-DI: 5901297NEFROCXN**	Class IIb implantable non-WET	Cobalt-Chromium Stent for Renal Vessels with delivery system, Rapid Exchange, Nefro C	EC Certificate: 145013-20-08-12 NB 2409

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
CORONARY ANGIOPLASTY CATHETER, RIVER **Rapid Exchange delivery system type** **Basic UDI-DI: 5901297CBRE3**	Class III	Coronary Angioplasty Catheter, Rapid Exchange, RIVER	EC Certificate: 145045-20-10-20 EC Design Certificate: 145046-20-10-20 NB 2409
CORONARY ANGIOPLASTY CATHETER, RIVER CTO **Basic UDI-DI: 5901297RIVERCTOH4**	Class III	Coronary Angioplasty Catheter, Rapid Exchange, RIVER CTO	EC Certificate: 145018-20-07-21 EC Design Certificate: 145019-20-07-21 NB 2409
NON-COMPLIANT CORONARY ANGIOPLASTY CATHETER, RIVER NC **Rapid Exchange delivery system type** **Basic UDI-DI: 5901297RIVERNC9S**	Class III	Coronary angioplasty catheter non-compliant type, Rapid Exchange, RIVER NC	EC Certificate: 145088-21-03-10 EC Design Certificate: 145089-21-03-10 NB 2409
VALVULOPLASTY CATHETER, VALVER **Basic UDI-DI: 5901297VALGK**	Class III	Valvuloplasty catheters Valver	EC Certificate: 145086-21-03-25 EC Design Certificate: 145087-21-03-25 NB 2409
Spinal Anaesthesia Needles and Sets: **SPINAL ANAESTHESIA SET** **Standard type** **SPINAL ANAESTHESIA NEEDLE** **Standard type** **SPINAL ANAESTHESIA SET** **Pencil-Point type**	Class III	Spinal Anaesthesia Needles and Sets	EC Certificate: 145041-20-10-20 EC Design Certificate: 145042-20-10-20 NB 2409

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SPINAL ANAESTHESIA NEEDLE **Pencil-Point type** **Basic UDI-DI: 5901297SPINALNEEDLES84**			
NEUROPROTECTION, ROBIN **Rapid Exchange delivery system type** **Basic UDI-DI: 5901297NEUROPROTECTIONMP**	Class III	Neuroprotection System ROBIN	EC Certificate: 145064-21-01-15 EC Design Certificate: 145065-21-01-15 NB 2409
Microspheres for embolization: **EMBOCURE MICROSPHERES** **EMBOCURE Plus MICROSPHERES** **Basic UDI-DI: 5901297MICROSPHERES4X**	Class III	Microspheres for embolization	EC Certificate: 145011-20-08-12 EC Certificate: 145012-20-08-12 NB 2409
ANGIOGRAPHY CATHETER **Basic UDI-DI: 5901297ANGIOGRAPHYRK**	Class III	Angiography catheters	EC Certificate: 145093-21-03-25 EC Design Certificate: 145094-21-03-25 NB 2409
INTRA-AORTIC BALLOON CATHETER SET **Basic UDI-DI: 5901297IABC2H**	Class III	Intra-Aortic Balloon Catheter Set	EC Certificate: 145095-21-03-25 EC Design Certificate: 145096-21-03-25 NB 2409
GUIDEWIRE WITH HYDROPHILIC COATING, PROVIDER	Class III	Guide wires with hydrophilic coating PROVIDER	EC Certificate: 145074-21-02-11

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 5901297PROVIDERLN			EC Design Certificate: 145075-21-02-11 NB 2409
SIROLIMUS ELUTING COBALT-CHROMIUM CORONARY STENT, ALEX STRATOS Rapid Exchange delivery system type **Basic UDI-DI: 5901297ALEXSTRATOS7M**	Class III	Cobalt-chromium sirolimus eluting coronary stent ALEX STRATOS with delivery system, Rapid Exchange	EC Certificate: 145104-21-03-29 EC Design Certificate: 145105-21-03-29 NB 2409
COBALT-CHROMIUM CORONARY STENT WITH DELIVERY SYSTEM RX, COFLEXUS **Basic UDI-DI: 5901297COFLEXUS83**	Class III	Cobalt-Chromium Coronary Stent CoFlexus with delivery system, Rapid Exchange	EC Certificate: 145023-20-08-12 EC Design Certificate: 145024-20-08-12 NB 2409
SIROLIMUS ELUTING CORONARY STENT WITH DELIVERY SYSTEM RX, PROLIM **Basic UDI-DI: 590129PROLIM65**	Class III	Sirolimus Eluting Coronary Stent PROLIM with Delivery System, Rapid Exchange	EC Certificate: 145043-20-10-20 EC Design Certificate: 145044-20-10-20 NB 2409
TEMPORARY TRANSVENOUS BIPOLAR PACING ELECTRODE **Basic UDI-DI: 5901297ELECTRODEH2**	Class III	Temporary Transvenous Bipolar Pacing Electrode	EC Certificate: 145097-21-03-25 EC Design Certificate: 145098-21-03-25 NB 2409
MECHANICAL THROMBECTOMY DEVICE Droser	Class III	Mechanical Thrombectomy Device, Droser	EC Certificate: 145143-21-05-22

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 590129DROSER2A			EC Design Certificate: 145144-21-05-22 NB 2409
CORONARY ANGIOPLASTY CATHETER, FRYDERYK Rapid Exchange delivery system type **Basic UDI-DI: 5901297FRYDERYKFC**	Class III	Coronary Angioplasty Catheter FRYDERYK, Rapid Exchange	EC Certificate: 145047-20-10-20 EC Design Certificate: 145048-20-10-20 NB 2409
PTCA Guidewire RIDER **Basic UDI-DI: 5901297RIDERZV**	Class III	PTCA Guide Wires with hydrophilic coating, RIDER	EC Certificate: 145077-21-03-25 EC Design Certificate: 145078-21-03-25 NB 2409
ENDOVASCULAR CATHETER FOR RETRIEVAL OF FOREIGN BODIES, Lasso **Basic UDI-DI: 5901297LASSOZJ**	Class III	Endovascular catheter for retrieval of foreign bodies LASSO / LASSO 3P	EC Certificate: 145079-21-03-25 EC Design Certificate: 145080-21-03-25 NB 2409

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-03-15	1	Initial issue

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 1023580-1
Certificate Holder:	BALTON sp. z o.o. Nowy Świat 7/14 00-496 Warszawa Poland
Scope:	Design and development, production and distribution of sterile, disposable medical devices for dialysis and haemodialysis, radiology, cardiology, urology, anaesthesiology, gynaecology and general surgery. Provision of EO sterilization service according to EN ISO 11135:2014 standard.

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

Report No.:	84970287-20
Effective date:	2023-12-03
Expiry date:	2026-12-02
Issue date:	2023-12-03

Replaces certificate SX 1023580-1 issued 2021-12-01

This certificate can be validated on https://www.certipedia.com

Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
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Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1023580-1

Certificate Holder: BALTON sp. z o.o.
Nowy Świat 7/14
00-496 Warszawa
Poland

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	BALTON sp. z o.o. Nowy Świat 7/14 00-496 Warszawa Poland	Administration.
/02	BALTON sp. z o.o. ul. Modlińska 294 03-152 Warszawa Poland	Design and development, production and distribution of sterile, disposable medical devices for dialysis,haemodialysis, radiology, cardiology, urology, anaesthesiology, gynaecology and general surgery.
/03	BALTON sp. z o.o. ul. Strzelnicza 3 18-300 Zambrów Poland	Production of disposable medical devices.
/04	BALTON sp. z o.o. ul. Topolowa 23 05-119 Łajski Poland	Production of metal elements for medical devices.Provision of EO sterilization service according to EN ISO 11135:2014 standard.

Report No.: 84970287-20

Effective date: 2023-12-03

Expiry date: 2026-12-02

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