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

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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

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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

Effective date: 2021-05-12

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Issue date: 2021-05-12

TÜV Rheinland LGA Products GmbH

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.

RA/32/2022

Declaration of Conformity

Revision 1

BALTON Sp. z o. o.
ul. Nowy Świat 7/14
00-496 Warszawa
POLAND
SRN: PL-MF-000010568

declares under its sole responsibility that the products mentioned in the product list attached to this declaration are labelled with the CE safety mark. The granting of the mark is confirmed by certificate no. HD 1023580-1 valid from 12 May 2021 issued by the certification body TUV Rheinland.
This declaration of conformity covers sterile I sterile and class II a.
The declaration is based on the implemented Quality Management System compliant with the requirements of the harmonized standards:

- N ISO 13485:2016, which is confirmed by certificate no. HD 1023580-1 valid as of May 12, 2021 by the certification body TUV Rheinland LGA Products GmbH.

In addition, we declare that the distributed CE marked products, classified as Class I sterile and Class IIa, meet the requirements of the applicable European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and the amendment Directive 2007/47/EC.
This declaration of conformity is valid for all products bearing the CE mark and manufactured in the locations listed below:

Headquarter:	ul. Nowy Świat 7/14, 00-496 Warszawa, Poland
Manufacturing plant 1:	ul. Modlińska 294, 03-152 Warszawa, Poland
Manufacturing plant 2:	ul. Strzelnicza 3, 99-100 Zambrów, Poland
Manufacturing plant 3:	ul. Topolowa 23, 05-119 Łajski, Poland

Annex 34

Ureteral catheters

No	Name of medical device	Reference
1	Ureteral catheter Couvelaire type (KMCVVXX) VV – sizes: 3, 4, 5, 6, 7, 8F XX – length: 110cm	KMC3F, KMC4F, KMC5F, KMC6F, KMC7F, KMC8F, KMC3FO, KMC4FO, KMC5FO KMC6FO, KMC7FO, KMC8FO, KMC3F110, KMC4F110, KMC5F110, KMC6F110, KMC7F110, KMC8F110
	Ureteral catheter Nelaton type (KMNVVXX) VV – sizes: 3, 4, 5, 6, 7, 8F XX – length: 110cm	KMN3F, KMN4F, KMN5F, KMN6F, KMN7F, KMN8F, KMN3FO, KMN4FO, KMN5FO, KMN6FO, KMN7FO, KMN8FO, KMN3F110, KMN4F110, KMN5F110, KMN6F110, KMN7F110, KMN8F110
	Ureteral catheter Tiemann type (KMTVVXX) VV – sizes: 3, 4, 5, 6, 7, 8F XX – length: 110cm	KMT3F, KMT4F, KMT5F, KMT6F, KMT7F, KMT8F, KMT3FO, KMT4FO, KMT5FO, KMT6FO, KMT7FO, KMT8FO, KMT3F110, KMT4F110, KMTF110, KMT6F110, KMT7F110, KMT8F110,
	Ureteral catheter X-Ray single Pigtail type (KMSVVXXo) VV – sizes: 3, 4, 5, 6, 7, 8F XX – length: 110cm o – distance between loops: 2,4	KMS3F702, KMS3F802, KMS4F702, KMS4F802, KMS5F702, KMS5F802, KMS6F702, KMS6F802, KMS7F702, KMS7F802, KMS8F702, KMS8F802, KMS3F704, KMS3F804, KMS4F704, KMS4F804, KMS5F704, KMS5F804, KMS6F704, KMS6F804, KMS7F704, KMS7F804, KMS8F704, KMS8F804
	Ureteral catheter X-Ray double Pigtail type (KMPVVXXo) VV – sizes: 3, 4, 5, 6, 7, 8F XX – length: 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30 o – distance between loops: 2,4	KMP3F102, KMP3F122, KMP3F142, KMP3F162, KMP3F182, KMP3F202, KMP3F222, KMP3F242, KMP3F262, KMP3F282, KMP3F302, KMP3F102O, KMP3F122O, KMP3F142O, KMP3F162O, KMP3F182O, KMP3F202O, KMP3F222O, KMP3F242O, KMP3F262O KMP3F282O, KMP3F302O, KMP3F102Z, KMP3F122Z, KMP3F142Z, KMP3F162Z, KMP3F182Z, KMP3F202Z, KMP3F222Z, KMP3F242Z, KMP3F262Z KMP3F282Z, KMP3F302Z, KMP3F102H, KMP3F122H, KMP3F142H, KMP3F162H, KMP3F182H, KMP3F202H, KMP3F222H, KMP3F242H, KMP3F262H, KMP3F282H,

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1023580-1

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

Scope: Design and development, production and distribution of sterile, disposable medical devices for dialysis and hemodialysis, radiology, cardiology, urology, anesthesiology, gynecology 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.: 84951149-20
Effective date: 2021-12-01
Expiry date: 2023-12-02
Issue date: 2021-12-01

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1023580-1

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

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	BALTON Sp. z o.o. ul. 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, hemodialysis, radiology, cardiology, urology, anesthesiology, gynecology 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 Wieliszew-Łajski Poland	Production of metal elements for medical devices. Provision of EO sterilization service according to EN ISO 11135:2014 standard.

Report No.: 84951149-20
Effective date: 2021-12-01
Expiry date: 2023-12-02
Issue date: 2021-12-01

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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