

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60144654 0001

Report No.: 26300250 012

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

Products: Sterile disposable medical devices
(see attachments for products and sites included)
Replaces EC Certificate. Registration No.: HD 60097877 0001

Expiry Date: 2024-05-26

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.

Effective Date: 2019-11-28

Date: 2019-11-28

Notified Body



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: HD 60144654 0001
Report No.: 26300250 012

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

Products:

- Analgetic control kits
- Angiographic accessories kits
- Aspiration catheters
- Balloon catheters
- Biliary prothesis, 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 trombectomy catheters
- Embolization catheters

Date: 2019-11-28

Notified Body

D. Swiatko



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/5, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60144654 0001
Report No.: 26300250 012

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

Products:

- Extenders
- Feeding catheters
- Flat antibacterial filters
- Guide wires
- Gynaecology 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

Date: 2019-11-28

Notified Body



D. Swiatko



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60144654 0001
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Manufacturer: **BALTON Sp. z o.o.**
Nowy Świat 7/14
00-496 Warszawa
Polska

Products:

- Ureteral catheters
- Urological catheters
- Vessel compression tourniquets
- Vessel irrigation catheters
- Vessel slings
- Sets for venous insufficiency treatment

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

Date: 2019-11-28

Notified Body



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 4/5, Rev. 0

**Attachment to
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Registration No.: HD 60144654 0001
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Nowy Świat 7/14
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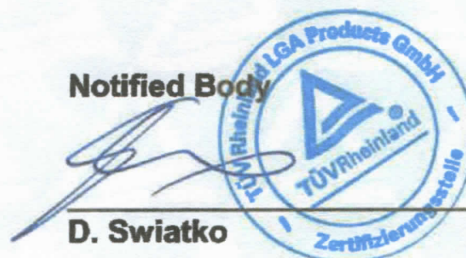
Products:

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

- Insemination catheter universal Luer-Lock caps
- Larynx anaesthesia catheters
- Luer-Lock caps
- Mandrins
- Pushers
- Redon plugs
- Radial artery compression tourniquet kits
- Stents for salivary ducts
- Suction connectors
- Universal hubs Luer-Lock

Date: 2019-11-28

Notified Body



D. Swiatko

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: HD 60144654 0001
Report No.: 26300250 012

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

Sites included:

BALTON Sp. z o.o.
ul. Modlinska 294
03-152 Warszawa, Poland
Scope: Design/development, manufacture

BALTON Sp. z o.o.
ul. Strzelnicza 3
18-300 Zambrow, Poland
Scope: Manufacture

BALTON Sp. z o.o.
ul. Topolowa 23
05-119 Lajski, Poland
Scope: Manufacture

Date: 2019-11-28

Notified Body



D. Swiatko

Certificate

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



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

Certificate

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