

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

Doc. 1/5, 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

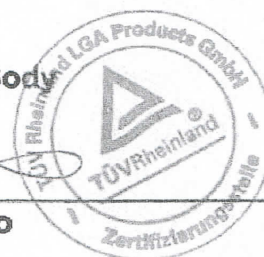
Products:

- Analgetic control kits
- Angiographic accessories kits
- Aspiration catheters
- Balloon catheters
- Biliary prothesis, catheters and kits
- Catheters and kits for dialysis
- Catheters for oxygen rhinoscopical 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**

**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:

- 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



Notified Body



D. Swiatko

Date: 2019-11-28

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

**Attachment to
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Registration No.: HD 60144654 0001
Report No.: 26300250 012

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

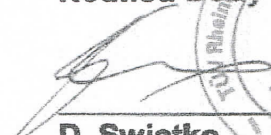

Products:

- 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

D. Swiatko


Zertifizierungsstelle



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 4/5, 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:

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



Notified Body



Date: 2019-11-28

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



Notified Body



Date: 2019-11-28

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

CE Certiso Ltd. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

Balton Sp. z o.o.

Headquarters: **00-496 Warszawa, ul. Nowy Świat 7/14, Poland**

Manufacturing plant: **03-152 Warszawa, ul. Modlińska 294, Poland**

Scope:

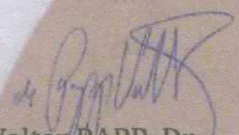
Sterile, disposable medical devices for cardiology, radiology, anaesthesiology, general surgery, urology, dialysis and gynecology; angioplasty catheters with or without active ingredient, stents with or without active ingredient with delivery system, self-expanding stents with delivery system and accessories.

This certificate is valid only with the annexes, in case of successfully conducted annual surveillance audits.

ID number of the related audit report: **126-CE-151016**

Issue: 1
Issued: 25 March 2016
First issued: 25 March 2016
Start date of certified status: 25 March 2016

Expires:
24 March 2021



Valter PAPP, Dr.
General Manager



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

BALTON Sp. z o.o.
ul. Nowy Swiat 7/14
00-496 Warszawa
Poland

has established and applies a quality management system for medical devices
for the following scope:

(see attachments for scope and sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-02-02
Certificate Registration No.: SX 60126763 0001
An audit was performed. Report No.: 26300250 006
This Certificate is valid until: 2021-12-02

Certification Body



Date 2018-02-02



Sebastian Mniszek

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/3, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60126763 0001
Report No.: 26300250 006

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

Scope:

Design and development, manufacture 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.



Certification Body

Date: 2018-02-02

Sebastian Mniszek

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/3, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60126763 0001
Report No.: 26300250 006

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

Scope:

Sites included:

BALTON Sp. z o.o.
ul. Modlinska 294
03-152 Warszawa, Poland

Activity: Design and development, manufacture
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.

BALTON Sp. z o.o.
ul. Strzelnicza 3
18-300 Zambrow, Poland
Activity: Manufacture of disposable medical devices.



Certification Body



Date: 2018-02-02

Sebastian Mniszek