

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

Registration No.: HD 60097877 0001

Report No.: 26300250 001

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

Products: Medical devices
(see attachments for products and sites included)
Replaces approval, registration no.: DD 60027691 0001

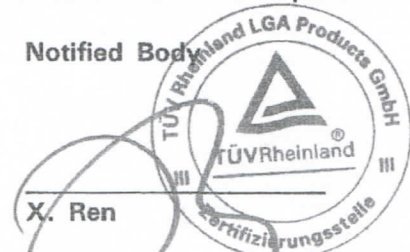
Expiry Date: 2019-12-02

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: 2014-12-03

Date: 2014-12-03

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 60097877 0001
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Manufacturer: BALTON Sp. z o.o.
ul. Nowy Swiat 7/14
00-496 Warszawa
Poland

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

Notified Body

Date: 2014-12-03



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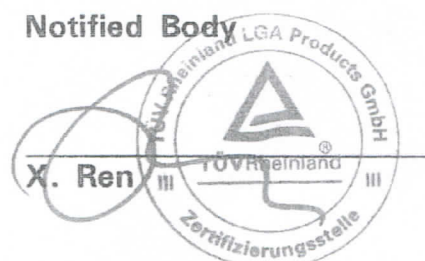
Manufacturer: BALTON Sp. z o.o.
ul. Nowy Swiat 7/14
00-496 Warszawa
Poland

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



Date: 2014-12-03

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Registration No.: HD 60097877 0001
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Manufacturer: **BALTON Sp. z o.o.**
ul. Nowy Swiat 7/14
00-496 Warszawa
Poland

Products:

- Ureteral catheters
- Urological catheters
- Vessel compression tourniquets
- Vessel irrigation catheters
- Vessel slings
- Large vessel catheterization catheters and kits

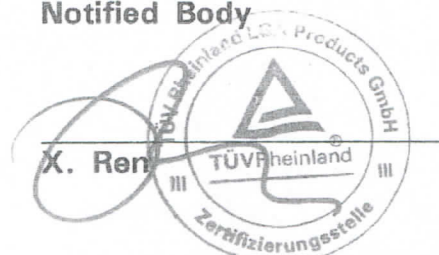
For the following medical devices, the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Aspirators
- Blockers
- Bottles, containers for aspiration
- Dilatation catheters for salivary ducts
- Endoscopic balloon dilation catheters
- Guide wire grips
- Guide wire introduction tubes



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Date: 2014-12-03



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Manufacturer: BALTON Sp. z o.o.
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Poland

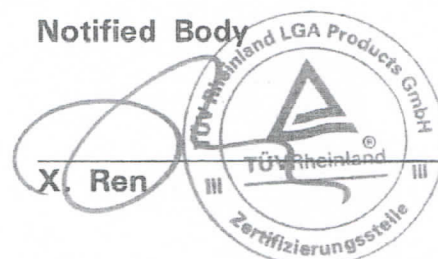
Products:

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: 2014-12-03





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 13485:2012
EN ISO 13485:2012/AC:2012

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

Effective Date: 2014-12-03
Certificate Registration No.: SX 60097878 0001
An audit was performed. Report No.: 26300250 001



Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2014-12-03



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

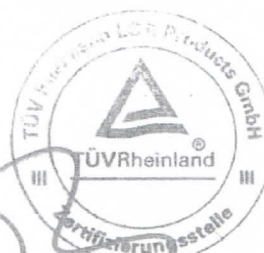
Attachment to
Registration No.: SX 60097878 0001
Report No.: 26300250 001

Organization: BALTON Sp. z o.o.
ul. Nowy Swiat 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 11135-1:2007 standard.



Certification Body



Date: 2014-12-03

X. Ren

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Registration No.: SX 60097878 0001
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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

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 11135-1:2007 standard.

Balton Sp. z o.o.
ul. Strzelnicza 3
18-300 Zambrow
Poland

Production of disposable medical devices.

Certification Body



Date: 2014-12-03

X. Ren