

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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:

- 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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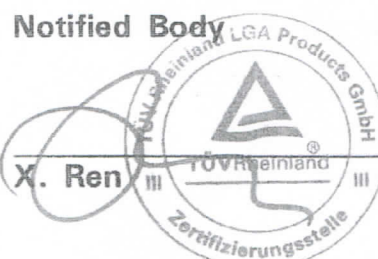
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Manufacturer: BALTON Sp. z o.o.
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Products:

- 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



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Products:

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

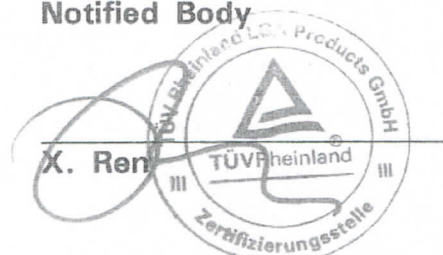
For the following medical devices, the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

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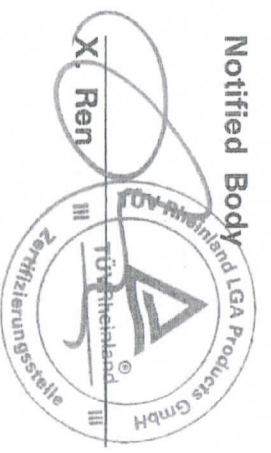
Manufacturer:
BALTON Sp. z o.o.
ul. Nowy Swiat 7/14
00-496 Warszawa
Poland

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

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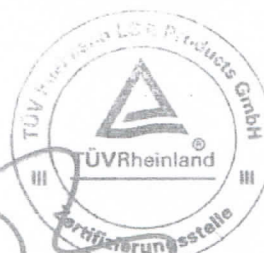
Attachment to
Registration No.: SX 60097878 0001
Report No.: 26300250 001

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

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: 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