

**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

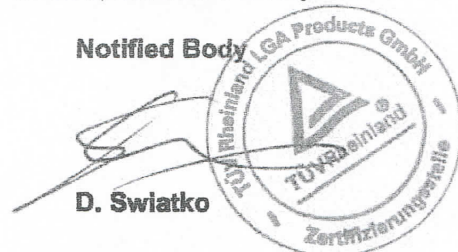
**Expiry Date:** 2024-05-26

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**

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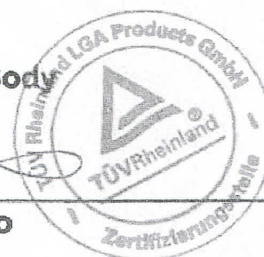
**Products:**

- 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**



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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
- 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

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Doc. 4/5, Rev. 0

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**Manufacturer:** BALTON Sp. z o.o.  
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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



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**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



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