

EC Certificate

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

Registration No.: HD 1023580-1

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

Products:

- Analgetic control kits
- Angiographic accessories kits
- Aspiration catheters
- Balloon catheters
- Biliary prosthesis, 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 thrombectomy catheters
- Embolization catheters

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.

Report No.: 84949468-50

Effective date: 2021-05-12

Expiry date: 2024-05-26

Issue date: 2021-05-12



Daniel Świątko
TÜV Rheinland LGA Products GmbH
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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ul. Nowy Świat 7/14
00-496 Warszawa
Poland

- Extenders
- Feeding catheters
- Flat antibacterial filters
- Guide wires
- Gynecology 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
- Ureteral catheters
- Urological catheters
- Vessel compression tourniquets
- Vessel irrigation catheters

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- Vessel slings
- Sets for venous insufficiency treatment
- Infusion microcatheters
- Support catheters

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
- Insemination catheter universal luer lock caps
- Larynx anesthesia catheters
- Luer lock caps
- Mandrins
- Pushers
- Redon plugs

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ul. Nowy Świat 7/14
00-496 Warszawa
Poland

- Radial artery compression tourniquet kits
- Stents for salivary ducts
- Suction connectors
- Universal hubs luer lock

Replaces EC Certificate, Registration No.: HD 60144654 0001

Report No.: 84949468-50

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Expiry date: 2024-05-26

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 ul. Nowy Świat 7/14
 00-496 Warszawa
 Poland

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	BALTON Sp. z o.o. ul. Nowy Świat 7/14 00-496 Warszawa Poland	Activity: Administration.
/02	BALTON Sp. z o.o. ul. Modlińska 294 03-152 Warszawa Poland	Activity: Design and development, production and distribution of sterile, disposable medical devices for dialysis and hemodialysis, radiology, cardiology, urology, anesthesiology, gynecology and general surgery.
/03	BALTON Sp. z o.o. ul. Strzelnicza 3 18-300 Zambrów Poland	Activity: Production of disposable medical devices.
/04	BALTON Sp. z o.o. ul. Topolowa 23 05-119 Łajski Poland	Activity: Production of components and packaging materials for disposable medical devices and EO gas sterilization service according to EN ISO 11135:2014 standard.

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