

# 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  
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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.

# 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

- 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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Effective date: 2021-05-12

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# 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

- 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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# 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

- 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

Effective date: 2021-05-12

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# 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

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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Issue date: 2021-05-12



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# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1023580-1

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

Scope: Design and development, production and distribution of sterile, disposable medical devices for dialysis and hemodialysis, radiology, cardiology, urology, anesthesiology, gynecology and general surgery.  
Provision of EO sterilization service according to EN ISO 11135:2014 standard.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84951149-20  
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Issue date: 2021-12-01



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# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1023580-1

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

The scope of certification includes the following additional sites:

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

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Issue date: 2021-12-01