

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/5, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60144654 0001
Report No.: 26300250 012

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

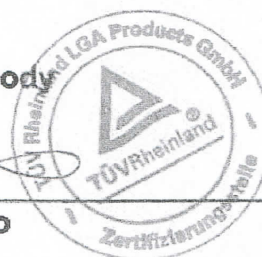
Products:

- 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



TÜV Rheinland
LGA Products GmbH
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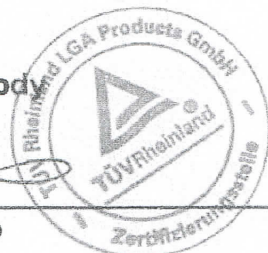
Products:

- 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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Nowy Świat 7/14
00-496 Warszawa
Polska

Sites included:

BALTON Sp. z o.o.
ul. Modlinska 294
03-152 Warszawa, Poland
Scope: Design/development, manufacture

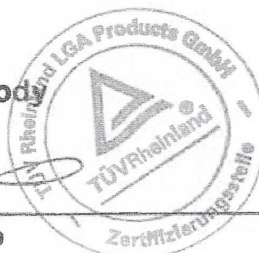
BALTON Sp. z o.o.
ul. Strzelnicza 3
18-300 Zambrow, Poland
Scope: Manufacture

BALTON Sp. z o.o.
ul. Topolowa 23
05-119 Lajski, Poland
Scope: Manufacture

Date: 2019-11-28

Notified Body

D. Swiatko



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

CE Certiso Ltd. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

Balton Sp. z o.o.

Headquarters:

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

Manufacturing plant:

03-152 Warszawa, ul. Modlińska 294, Poland

Scope:

Sterile, disposable medical devices for cardiology, radiology, anaesthesiology, general surgery, urology, dialysis and gynecology; angioplasty catheters with or without active ingredient, stents with or without active ingredient with delivery system, self-expanding stents with delivery system and accessories.

This certificate is valid only with the annexes, in case of successfully conducted annual surveillance audits.

ID number of the related audit report: **126-CE-151016**

Issue: 1

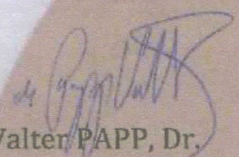
Issued: 25 March 2016

First issued: 25 March 2016

Start date of certified status: 25 March 2016

Expires:

24 March 2021


Valter PAPP, Dr.
General Manager



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 13485:2016

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

Effective Date: 2018-02-02
Certificate Registration No.: SX 60126763 0001
An audit was performed. Report No.: 26300250 006
This Certificate is valid until: 2021-12-02



Certification Body



Date 2018-02-02



Sebastian Mniszek

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

Doc. 1/3, Rev. 0

**Attachment to
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Registration No.: SX 60126763 0001
Report No.: 26300250 006

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

Scope:

Design and development, manufacture 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 11135:2014 standard.



Certification Body

Date: 2018-02-02

Sebastian Mniszek

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

Scope:

Sites included:

BALTON Sp. z o.o.
ul. Modlinska 294
03-152 Warszawa, Poland

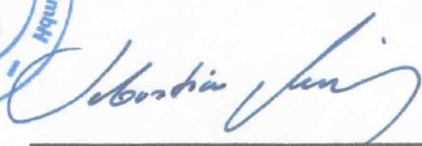
Activity: Design and development, manufacture
and distribution of sterile, disposable medical
devices for dialysis and haemodialysis, radiology,
cardiology, urology, anaesthesiology, gynaecology
and general surgery.
Provision of EO sterilization service according
to EN ISO 11135:2014 standard.

BALTON Sp. z o.o.
ul. Strzelnicza 3
18-300 Zambrow, Poland
Activity: Manufacture of disposable medical devices.



Certification Body

Date: 2018-02-02


Sebastian Mniszek



00-496 Warszawa, POLAND
ul. Nowy Świat 7/14
tel: +48 22 625 32 15
fax: +48 22 621 58 14

03-152 Warszawa, POLAND
ul. Modlińska 294
tel: +48 22 597 44 00
fax: +48 22 597 44 44

Declaration of Conformity

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

We declare under our sole responsibility that:

The Medical Device: Introducers version braided and non-braided - kits to introduce and exchange catheters and endocavitary electrodes with or without hemostasis valve,

Models: INT3F, INT3F6, INT3F11, INT3F23, INT3F35, INT3.5F, INT4F, INT4F11, INT4F23, INT4F35, INT4.5F, INT5F, INT5F5, INT5F6, INT5F6.5, INT5F7, INT5F7.5, INT5F23, INT5F35, INT5F40, INT5F45, INT5F50, INT5F55, INT5F60, INT5F65, INT5F70, INT5F80, INT5F90, INT5.5F, INT5.5F5, INT5.5F23, INT6F, INT6F12, INT6F5.5, INT6F7, INT6F7.5, INT6F23, INT6F35, INT6F40, INT6F45, INT6F50, INT6F55, INT6F60, INT6F65, INT6F70, INT6F80, INT6F90, INT6.5F, INT6.5F23, INT6.5F35, INT6.5F40, INT6.5F45, INT6.5F50, INT6.5F55, INT6.5F60, INT6.5F65, INT6.5F70, INT6.5F80, INT6.5F90, INT7F, INT7F12, INT7F23, INT7F35, INT7F40, INT7F43, INT7F45, INT7F5.5, INT7F6, INT7F6.5, INT7F50, INT7F55, INT7F60, INT7F65, INT7F70, INT7F80, INT7F90, INT7.5F, INT7.5F12, INT7.5F23, INT7.5F35, INT7.5F40, INT7.5F43, INT7.5F45, INT7.5F5.5, INT7.5F6, INT7.5F6.5, INT7.5F50, INT7.5F55, INT7.5F60, INT7.5F65, INT7.5F70, INT7.5F80, INT7.5F90, INT8F, INT8F23, INT8F35, INT8F40, INT8F43, INT8F45, INT8F50, INT8F55, INT8F60, INT8F65, INT8F70, INT8F80, INT8F90, INT8.5F, INT9F, INT9F23, INT9F35, INT9.5F, INT9.5F23, INT9.5F35, INT10F, INT10F23, INT10F35, INT10.5F, INT10.5F23, INT10.5F35, INT11F, INT11F23, INT11F35, INT11.5F, INT11.5F23, INT11.5F35, INT12F, INT12F23, INT12F35, INT12.5F, INT12.5F23, INT12.5F35, INT14F, INT14F23, INT14F35, INT14.5F, INT14.5F23, INT14.5F35, INT16F, INT16F23, INT16F35, INT16.5F, INT16.5F23, INT16.5F35, INT18F, INT18F23, INT18F35, INT3FH, INT3F6H, INT3F11H, INT3F23H, INT3F35H, INT3.5FH, INT4FH, INT4F11H, INT4F23H, INT4F35H, INT4.5FH, INT5FH, INT5F5H, INT5F6H, INT5F6.5H, INT5F7H, INT5F7.5H, INT5F23H, INT5F35H, INT5F40H, INT5F45H, INT5F50H, INT5F55H, INT5F60H, INT5F65H, INT5F70H, INT5F80H, INT5F90H, INT5.5FH, INT5.5F5H, INT5.5F23H, INT6FH, INT6F12H, INT6F5.5H, INT6F7H, INT6F7.5H, INT6F23H, INT6F35H, INT6F40H, INT6F45H, INT6F50H, INT6F55H, INT6F60H, INT6F65H, INT6F70H, INT6F80H, INT6F90H, INT6.5FH, INT6.5F23H, INT6.5F35H, INT6.5F40H, INT6.5F45H, INT6.5F50H, INT6.5F55H, INT6.5F60H, INT6.5F65H, INT6.5F70H, INT6.5F80H, INT6.5F90H, INT7FH, INT7F12H, INT7F23H, INT7F35H, INT7F40H, INT7F43H, INT7F45H, INT7F5.5H, INT7F6H, INT7F6.5H, INT7F50H, INT7F55H, INT7F60H, INT7F65H, INT7F70H, INT7F80H, INT7F90H, INT7.5FH, INT7.5F12H, INT7.5F23H, INT7.5F35H, INT7.5F40H, INT7.5F43H, INT7.5F45H, INT7.5F5.5H, INT7.5F6H, INT7.5F6.5H, INT7.5F50H, INT7.5F55H, INT7.5F60H, INT7.5F65H, INT7.5F70H, INT7.5F80H, INT7.5F90H, INT8FH, INT8F23H, INT8F35H, INT8F40H, INT8F43H, INT8F45H, INT8F50H, INT8F55H, INT8F60H, INT8F65H, INT8F70H, INT8F80H, INT8F90H, INT8.5FH, INT9FH, INT9F23H, INT9F35H, INT9.5FH, INT9.5F23H, INT9.5F35H, INT10FH, INT10F23H, INT10F35H, INT10.5FH, INT10.5F23H, INT10.5F35H, INT11FH, INT11F23H, INT11F35H, INT11.5FH, INT11.5F23H, INT11.5F35H, INT12FH, INT12F23H, INT12F35H, INT12.5FH, INT12.5F23H, INT12.5F35H, INT14FH, INT14F23H, INT14F35H, INT14.5FH, INT14.5F23H, INT14.5F35H, INT16FH, INT16F23H, INT16F35H, INT16.5FH, INT16.5F23H, INT16.5F35H, INT18FH, INT18F23H, INT18F35H, INT3FT, INT3F6T, INT3F11T, INT3.5FT, INT4FT, INT4F11T, INT4F40T, INT4F45T, INT4F50T, INT4F60T, INT4F70T, INT4F80T, INT4F90T, INT4F100T, INT4.5FT, INT5FT, INT5F5T, INT5F6T, INT5F6.5T, INT5F7T, INT5F7.5T, INT5F40T, INT5F45T, INT5F50T, INT5F60T, INT5F70T, INT5F80T, INT5F90T, INT5F100T, INT5.5FT, INT5.5F5T, INT5.5F7.5T, INT5.5F23T, INT5.5F40T, INT5.5F45T, INT5.5F50T, INT5.5F60T, INT5.5F70T, INT5.5F80T, INT5.5F90T, INT5.5F100T, INT6FT, INT6F12T, INT6F5.5T, INT6F7T, INT6F7.5T, INT6F23T, INT6F40T, INT6F45T, INT6F50T, INT6F60T, INT6F70T, INT6F80T, INT6F90T, INT6F100T, INT6.5FT, INT6.5F12T, INT6.5F5.5T, INT6.5F7T, INT6.5F7.5T, INT6.5F23T, INT6.5F40T, INT6.5F45T, INT6.5F50T, INT6.5F60T, INT6.5F70T, INT6.5F80T, INT6.5F90T, INT6.5F100T, INT7FT, INT7F12T, INT7F23T, INT7F40T, INT7F43T, INT7F45T, INT7F5.5T, INT7F6T, INT7F6.5T, INT7F50T, INT7F60T, INT7F70T, INT7F80T, INT7F90T, INT7F100T, INT7.5FT, INT7.5F12T, INT7.5F40T, INT7.5F43T, INT7.5F45T, INT7.5F5.5T, INT7.5F6T, INT7.5F6.5T, INT7.5F50T, INT7.5F60T, INT7.5F70T, INT7.5F80T, INT7.5F90T, INT7.5F100T, INT7.5F23T, INT8FT, INT8F23T, INT8F40T, INT8F45T, INT8F50T, INT8F60T, INT8F70T, INT8F80T, INT8F90T, INT8F100T, INT8.5FT, INT8.5F23T, INT8.5F40T, INT8.5F45T, INT8.5F50T, INT8.5F60T, INT8.5F70T, INT8.5F80T, INT8.5F90T, INT8.5F100T, INT9FT, INT9F23T, INT9F40T, INT9F45T, INT9F50T, INT9F60T, INT9F70T, INT9F80T, INT9F90T, INT9F100T, INT9.5FT, INT9.5F23T, INT9.5F40T, INT9.5F45T, INT9.5F50T, INT9.5F60T, INT9.5F70T, INT9.5F80T, INT9.5F90T, INT9.5F100T, INT10FT, INT10F23T, INT10F40T, INT10F45T, INT10F50T, INT10F60T, INT10F70T, INT10F80T, INT10F90T, INT10F100T, INT11FT, INT11F23T, INT11F40T, INT11F45T, INT11F50T, INT11F60T, INT11F70T, INT11F80T, INT11F90T, INT11F100T, INT12FT, INT12F23T, INT12F40T, INT12F45T, INT12F50T, INT12F60T, INT12F70T, INT12F80T, INT12F90T, INT12F100T, INT14FT, INT14F23T, INT14F40T, INT14F45T, INT14F50T, INT14F60T, INT14F70T, INT14F80T, INT14F90T, INT14F100T, INT16FT, INT16F23T, INT16F40T, INT16F45T, INT16F50T, INT16F60T, INT16F70T, INT16F80T, 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INT11FM, INT11F23M, INT11F35M, INT11.5FM, INT11.5F23M, INT11.5F35M, INT12FM, INT12F23M, INT12F35M, INT12.5FM, INT12.5F23M, INT12.5F35M, INT14FM, INT14F23M, INT14F35M, INT14.5FM, INT14.5F23M, INT14.5F35M, INT16FM, INT16F23M, INT16F35M, INT16.5FM, INT16.5F23M, INT16.5F35M, INT18FM, INT18F23M, INT18F35M, INT3FHM, INT3F6HM, INT3F11HM, INT3F23HM, INT3F35HM, INT3.5FHM, INT4FHM, INT4F11HM, INT4F23HM, INT4F35HM, INT4.5FHM, INT5FHM, INT5F5HM, INT5F6HM, INT5F6.5HM, INT5F7HM, INT5F7.5HM, INT5F23HM, INT5F35HM, INT5F40HM, INT5F45HM, INT5F50HM, INT5F55HM, INT5F60HM, INT5F65HM, INT5F70HM, INT5F80HM, INT5F80HM, INT5F90HM, INT5.5FHM, INT5.5F5HM, INT5.5F23HM, INT6FHM, INT6F12HM, INT6F5.5HM, INT6F7HM, INT6F7.5HM, INT6F23HM, INT6F35HM, INT6F40HM, INT6F45HM, INT6F50HM, INT6F55HM, INT6F60HM, INT6F65HM, INT6F70HM, INT6F80HM, INT6F90HM, INT6.5FHM, INT6.5F23HM, INT6.5F35HM, INT6.5F40HM, INT6.5F45HM, INT6.5F50HM, INT6.5F55HM, INT6.5F60HM, INT6.5F65HM, INT6.5F70HM, INT6.5F80HM, INT6.5F90HM, INT7FHM, INT7F12HM, 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INT6.5F23BI, INT6.5F35BI, INT6.5F40BI, INT6.5F45BI, INT6.5F50BI, INT6.5F55BI, INT6.5F60BI, INT6.5F65BI, INT6.5F70BI, INT6.5F80BI, INT6.5F90BI, INT7FBI, INT7F12BI, INT7F23BI, INT7F35BI, INT7F40BI, INT7F43BI, INT7F45BI, INT7F5.5BI, INT7F6BI, INT7F6.5BI, INT7F50BI, INT7F55BI, INT7F60BI, INT7F65BI, INT7F70BI, INT7F80BI, INT7F90BI, INT7.5FBI, INT7.5F12BI, INT7.5F23BI, INT7.5F35BI, INT7.5F40BI, INT7.5F43BI, INT7.5F45BI, INT7.5F5.5BI, INT7.5F6BI, INT7.5F6.5BI, INT7.5F50BI, INT7.5F55BI, INT7.5F60BI, INT7.5F65BI, INT7.5F70BI, INT7.5F80BI, INT7.5F90BI, INT8FBI, INT8F23BI, INT8F35BI, INT8F40BI, INT8F43BI, INT8F45BI, INT8F50BI, INT8F55BI, INT8F60BI, INT8F65BI, INT8F70BI, INT8F80BI, INT8F90BI, INT8.5FBI, INT9FBI, INT9F23BI, INT9F35BI, INT9.5FBI, INT9.5F23BI, INT9.5F35BI, INT10FBI, INT10F23BI, INT10F35BI, INT10.5FBI, INT10.5F23BI, INT10.5F35BI, TKATINT, ZWERK6F, ZWERK6.5F, ZWERK7F, ZWERK7.5F, ZWERK8F, ZWERK8.5F, ZWERK9F, ZWERK9.5F, ZWERK10F, ZWERK10.5F, ZWERK11F, ZWERK11.5F, ZWERK12F, ZWERK13F, ZWERK14F, ZWERK15F, ZWERK16F

of Class II a, rule 6 according to Annex IX of 93/42/EEC Directive

covered by the Technical Files rev. 09, dated 2011

product releasing documentation: Departmental Norm No 01/1996, edit VII, Technological Instruction No 177, 178, 179 and Lot Report No BA 177, 178, 179 which is considered as a part of this declaration

meets the provisions of the directive 93/42/EEC which apply to them.

UMDNS CODE: 17-578

APPLIED HARMONIZED STANDARDS:

EN 556-1: 2001+AC:2006, EN ISO 15223-1:2016, EN 1041:2008/A1:2013, EN ISO 80369-7:2017, ISO 2859-1: 1999/Amd1:2011, EN ISO 7864:2016, EN ISO 9626: 2016, EN ISO 10555-1:2013, EN ISO 10555-3:2013, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-4:2009, EN ISO 10993-5:2009, EN ISO 10993-7:2008+AC:2009, EN ISO 10993-10:2013, EN ISO 10993-11:2009, EN ISO 11070:2014, EN ISO 11135:2014, EN ISO 11607-1:2017, EN ISO 11607-2:2017, EN ISO 11737-1:2006/AC:2009, EN ISO 13485: 2016, EN ISO 14971:2012, EN 62366-1:2015,

Conformity assessment procedure: Annex V of 93/42/EEC directive

NOTIFIED BODY: TÜV Rheinland LGA Product GmbH,
Tillystraße 2, 90431 Nürnberg
Identification Number 0197,

CERTIFICATES: EN ISO 13485:2016 No SX 60126763 0001

EC CERTIFICATE: Approval EC Directive 93/42/EEC, Annex II, excluding Section 4
Quality Assurance System Production, No HD 60097877 0001

Warsaw, December 21, 2018

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