

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
Certificate**

Registration No.: SX 60126763 0001
Report No.: 26300250 006

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

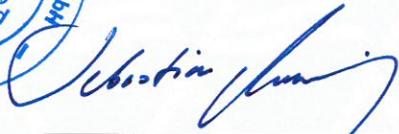
Scope:

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

Doc. 2/3, Rev. 0

**Attachment to
Certificate**

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:

Sites included:

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

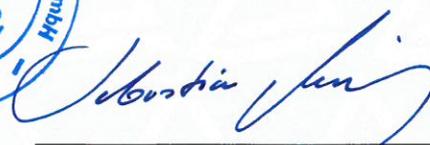
Activity: Design and development, manufacture
and distribution of sterile, disposable medical
devices for dialysis and haemodialysis, radiology,
cardiology, urology, anaesthesiology, gynaecology
and general surgery.

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.

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Sebastian Mniszek

Date: 2018-02-02

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/3, 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:

Sites included:

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

Activity: Manufacture of metal elements for medical devices.
Provision of EO sterilization service according
to EN ISO 11135:2014 standard.

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Date: 2018-02-02

Sebastian Mniszek