TÜVRheinland®

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

Digitally signed by Iarovoi Petru
Date: 2019.12.03 15:48:15 EET
Reason: MoldSign Signature
Location: Moldova

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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.

FIRMA DE PRODUCERE SI COMERT "SOGNO" S.R.L. • IDNO 1004600013654 • REPUBLICA MOLDOVA, mun. CHISINAU • Sogno S.R.L.

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Date: 2018-02-02

Sebastian Mniszek

TÜVRheinland®

Doc. 2/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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.

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2018-02-02

Sebastian Mniszek

144612-16-03-25

EC CERTIFICATE

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

CE Certiso Ltd.
H-2040 Budaörs, Gyár u. 2.
Tel.: +36 23 880 830 / Fax: +36 23 880 831 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Spinal Anaesthesia Needles	Standard	for subarachnoid anaesthesia and to perform diagnostic lumbar punctures.	IPP*SDxL* where *S= Standard* *D*= diameter (18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 29G) *L*= length (50, 75, 90, 130mm)	III*
	Pencil-point		IPP*WDxL* where *W= Pencil-point* *D*= diameter (22G, 24G, 25G, 26G, 27G) *L*= length (90, 120mm)	III*
Spinal Anaesthesia Sets	Standard		ZIPP*SDxL* where *S= Standard* *D*= diameter (18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 29G) *L*= length (90, 130mm)	III*
	Pencil-point		ZIPP*WDxL* where *W= Pencil-point* *D*= diameter (22G, 24G, 25G, 26G, 27G) *L*= length (90, 120mm)	III*

*In case of devices in Class III, this certificate independently does not authorize the manufacturer for the use of CE mark on the devices.

Issue: 1
Issued: 13 December 2016

Valter PAPP, Dr.
General Manager

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L. REPUBLICA MOLDOVA
Sogno S.R.L. IDNO 1004800012654

CE Certiso Ltd. NB2409 Notified Body

CE Certiso Ltd.
H-2040 Budaörs, Gyár u. 2.
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NB ID number: 2409