Digitally signed by Iarovoi Petru
Date: 2022.11.11 17:19:58 EET
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Location: Moldova

145081-21-03-25

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

Manufacturing plants: **ul. Modlińska 294, 03-152 Warszawa, Poland**

ul. Topolowa 23, 05-119 Łajski, Poland

Scope:

Large Vessel Catheterization Catheters and Kits

Description of the device	Type	Intended use	Model	Risk class
Large vessel catheterization catheters and kits	single lumen with split cannula, pediatric	for intravenous therapy when peripheral venous access is impossible	**KKDN, ZKDN, KKDND, ZKDND, KKDNT, ZKDNT, KKDNIV, ZKDNIV,**	III
	single lumen, pediatric			
	single lumen			
	double lumen			
	triple lumen			
	quadruple lumen			

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

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

ID number of the related audit report: **126-CE-190115**
Issue: 1
Issued: 25 March 2021
First issued: 25 March 2021
Start date of certified status: 27 March 2018

CE Certiso
Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Valter PAPP, Dr.
General Manager

Expires:
25 May 2024

CE Certiso Ltd. NB2409 Notified Body

CE Certiso Kft.
H-2092 Budakeszi, Erdő u. 101.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409

Certificate

TÜVRheinland®

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
Effective date: 2021-12-01
Expiry date: 2023-12-02
Issue date: 2021-12-01

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

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.

Report No.: 84951149-20
Effective date: 2021-12-01
Expiry date: 2023-12-02
Issue date: 2021-12-01

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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