

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:

Anaesthesia Sets

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Anaesthesia Sets	Epidural anaesthesia set small	Epidural anaesthesia sets are intended for the introduction of analgetic agents or opiates	ZZOM, ZZOR, ZZK, IT, KE (See annex)	III*
	Epidural anaesthesia set advanced			
	Combined anaesthesia set advanced			
	Combined anaesthesia set small			
	Epidural anaesthesia set with accessories for spinal and combined anaesthesia			
	Tuohy needle			
	Epidural catheter			

*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 the 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: 16 August 2017

Expires:

25 May 2024

The certificate covers the following devices:

Epidural anaesthesia set small

Codes:

- ZZOM16G, ZZOM17G, ZZOM18G, ZZOM19G
- ZZOM16GS, ZZOM17GS, ZZOM18GS, ZZOM19GS (*soft tip*)
- ZZOM16GSN, ZZOM17GSN, ZZOM18GSN, ZZOM19GSN (*low resistance syringe*)
- ZZOM16GSSN, ZZOM17GSSN, ZZOM18GSSN, ZZOM19GSSN (*soft tip + low resistance syringe*)
- ZZOM16GEM, ZZOM17GEM, ZZOM18GEM, ZZOM19GEM (*catheter fixing element*)
- ZZOM16GSEM, ZZOM17GSEM, ZZOM18GSEM, ZZOM19GSEM (*soft tip + catheter fixing element*)
- ZZOM16GSNEM, ZZOM17GSNEM, ZZOM18GSNEM, ZZOM19GSNEM (*low resistance syringe + catheter fixing element*)
- ZZOM16GSSNEM, ZZOM17GSSNEM, ZZOM18GSSNEM, ZZOM19GSSNEM (*soft tip + low resistance syringe + catheter fixing element*)

Epidural anaesthesia set advanced

Codes:

- ZZOR16G, ZZOR17G, ZZOR18G, ZZOR19G
- ZZOR16GS, ZZOR17GS, ZZOR18GS, ZZOR19GS (*soft tip*)
- ZZOR16GEM, ZZOR17GEM, ZZOR18GEM, ZZOR19GEM (*catheter fixing element*)
- ZZOR16GSEM, ZZOR17GSEM, ZZOR18GSEM, ZZOR19GSEM (*soft tip + catheter fixing element*)

Epidural anaesthesia set with accessories for spinal and combined anaesthesia

Codes:

- ZZOR16GD, ZZOR17GD, ZZOR18GD, ZZOR19GD
- ZZOR16GSD, ZZOR17GSD, ZZOR18GSD, ZZOR19GSD (*soft tip*)

Issue: 1
Issued: 25 March 2021

Valter PAPP, Dr.
General Manager

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

The certificate covers the following devices:

Combined anaesthesia set advanced

Codes:

- ZZOR16GI26130, ZZOR16GI2690, ZZOR16GI2690W, ZZOR16GI27130, ZZOR16GI27120, ZZOR16GI2790, ZZOR16GI27120W, ZZOR16GI2790W, ZZOR18GI26130, ZZOR18GI2690, ZZOR18GI2690W, ZZOR18GI27130, ZZOR18GI27120, ZZOR18GI2790, ZZOR18GI27120W, ZZOR18GI2790W
- ZZOR16GSI26130, ZZOR16GSI2690, ZZOR16GSI2690W, ZZOR16GSI27130, ZZOR16GSI27120, ZZOR16GSI2790, ZZOR16GSI27120W, ZZOR16GSI2790W, ZZOR18GSI26130, ZZOR18GSI2690, ZZOR18GSI2690W, ZZOR18GSI27130, ZZOR18GSI27120, ZZOR18GSI2790, ZZOR18GSI27120W, ZZOR18GSI2790W (soft tip)
- ZZOR16GSI26130EM, ZZOR16GSI2690EM, ZZOR16GSI2690WEM, ZZOR16GSI27130EM, ZZOR16GSI27120EM, ZZOR16GSI2790EM, ZZOR16GSI27120WEM, ZZOR16GSI2790WEM, ZZOR18GSI26130EM, ZZOR18GSI2690EM, ZZOR18GSI2690WEM, ZZOR18GSI27130EM, ZZOR18GSI27120EM, ZZOR18GSI2790EM, ZZOR18GSI27120WEM, ZZOR18GSI2790WEM, ZZOR16GI26130EM, ZZOR16GI2690EM, ZZOR16GI2690WEM, ZZOR16GI27130EM, ZZOR16GI27120EM, ZZOR16GI2790EM, ZZOR16GI27120WEM, ZZOR16GI2790WEM, ZZOR18GI26130EM, ZZOR18GI2690EM, ZZOR18GI2690WEM, ZZOR18GI27130EM, ZZOR18GI27120EM, ZZOR18GI2790EM, ZZOR18GI27120WEM, ZZOR18GI2790WEM (catheter fixing element)

Combined anaesthesia set –small

Codes:

- ZZK16G, ZZK18G

Tuohy needle

Codes:

- IT16G, IT17G, IT18G, IT19G

Epidural catheter

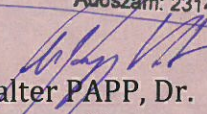
Codes:

- KE18G, KE19G, KE20G, KE22G, KE18GS, KE19GS, KE20GS

Issue: 1

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


Valter PAPP, Dr.
General Manager

EC DESIGN-EXAMINATION CERTIFICATE

Directive 93/42/EEC on Medical devices, Annex II (4)

CE Certiso Ltd. (NB 2409) certifies that the design of the device concerning to the listed devices and device categories conforms to the 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:

Anaesthesia Sets

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Anaesthesia Sets	Epidural anaesthesia set small	Epidural anaesthesia sets are intended for the introduction of analgetic agents or opiates	ZZOM, ZZOR, ZZK, IT, KE (See annex)	III*
	Epidural anaesthesia set advanced			
	Combined anaesthesia set advanced			
	Combined anaesthesia set small			
	Epidural anaesthesia set with accessories for spinal and combined anaesthesia			
	Tuohy needle			
Epidural catheter				

This certificate is valid only with the annexes and the system certificate No. **145084-21-03-25**, in case of successfully conducted annual surveillance audits.

ID number of the related design examination report: 126-G20-190115

Issue: 1

Issued: 25 March 2021

First issued: 25 March 2021

Start date of certified status: 16 August 2017

Expires:

25 May 2024

CE Certiso

Orvos- és Kórháztechnikai

Ellenőrző és Tanúsító Kft.

H-2092 Budakeszi, Erdő u. 101.

Reg. szám: 23147049-2-13

Valter PAPP, MD

General Manager

The certificate covers the following devices:

Epidural anaesthesia set small

Codes:

- ZZOM16G, ZZOM17G, ZZOM18G, ZZOM19G
- ZZOM16GS, ZZOM17GS, ZZOM18GS, ZZOM19GS (*soft tip*)
- ZZOM16GSN, ZZOM17GSN, ZZOM18GSN, ZZOM19GSN (*low resistance syringe*)
- ZZOM16GSSN, ZZOM17GSSN, ZZOM18GSSN, ZZOM19GSSN (*soft tip + low resistance syringe*)
- ZZOM16GEM, ZZOM17GEM, ZZOM18GEM, ZZOM19GEM (*catheter fixing element*)
- ZZOM16GSEM, ZZOM17GSEM, ZZOM18GSEM, ZZOM19GSEM (*soft tip + catheter fixing element*)
- ZZOM16GSNEM, ZZOM17GSNEM, ZZOM18GSNEM, ZZOM19GSNEM (*low resistance syringe + catheter fixing element*)
- ZZOM16GSSNEM, ZZOM17GSSNEM, ZZOM18GSSNEM, ZZOM19GSSNEM (*soft tip + low resistance syringe + catheter fixing element*)

Epidural anaesthesia set advanced

Codes:

- ZZOR16G, ZZOR17G, ZZOR18G, ZZOR19G
- ZZOR16GS, ZZOR17GS, ZZOR18GS, ZZOR19GS (*soft tip*)
- ZZOR16GEM, ZZOR17GEM, ZZOR18GEM, ZZOR19GEM (*catheter fixing element*)
- ZZOR16GSEM, ZZOR17GSEM, ZZOR18GSEM, ZZOR19GSEM (*soft tip + catheter fixing element*)

Epidural anaesthesia set with accessories for spinal and combined anaesthesia


Codes:

- ZZOR16GD, ZZOR17GD, ZZOR18GD, ZZOR19GD
- ZZOR16GSD, ZZOR17GSD, ZZOR18GSD, ZZOR19GSD (*soft tip*)

Issue: 1

Issued: 25 March 2021

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H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13



Valter PAPP, Dr.
General Manager



The certificate covers the following devices:

Combined anaesthesia set advanced

Codes:

- ZZOR16GI26130, ZZOR16GI2690, ZZOR16GI2690W, ZZOR16GI27130, ZZOR16GI27120, ZZOR16GI2790, ZZOR16GI27120W, ZZOR16GI2790W, ZZOR18GI26130, ZZOR18GI2690, ZZOR18GI2690W, ZZOR18GI27130, ZZOR18GI27120, ZZOR18GI2790, ZZOR18GI27120W, ZZOR18GI2790W
- ZZOR16GSI26130, ZZOR16GSI2690, ZZOR16GSI2690W, ZZOR16GSI27130, ZZOR16GSI27120, ZZOR16GSI2790, ZZOR16GSI27120W, ZZOR16GSI2790W, ZZOR18GSI26130, ZZOR18GSI2690, ZZOR18GSI2690W, ZZOR18GSI27130, ZZOR18GSI27120, ZZOR18GSI2790, ZZOR18GSI27120W, ZZOR18GSI2790W (*soft tip*)
- ZZOR16GSI26130EM, ZZOR16GSI2690EM, ZZOR16GSI2690WEM, ZZOR16GSI27130EM, ZZOR16GSI27120EM, ZZOR16GSI2790EM, ZZOR16GSI27120WEM, ZZOR16GSI2790WEM, ZZOR18GSI26130EM, ZZOR18GSI2690EM, ZZOR18GSI2690WEM, ZZOR18GSI27130EM, ZZOR18GSI27120EM, ZZOR18GSI2790EM, ZZOR18GSI27120WEM, ZZOR18GSI2790WEM, ZZOR16GI26130EM, ZZOR16GI2690EM, ZZOR16GI2690WEM, ZZOR16GI27130EM, ZZOR16GI27120EM, ZZOR16GI2790EM, ZZOR16GI27120WEM, ZZOR16GI2790WEM, ZZOR18GI26130EM, ZZOR18GI2690EM, ZZOR18GI2690WEM, ZZOR18GI27130EM, ZZOR18GI27120EM, ZZOR18GI2790EM, ZZOR18GI27120WEM, ZZOR18GI2790WEM (*catheter fixing element*)

Combined anaesthesia set -small

Codes:

- ZZK16G, ZZK18G

Tuohy needle

Codes:

- IT16G, IT17G, IT18G, IT19G

Epidural catheter

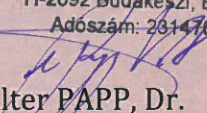
Codes:

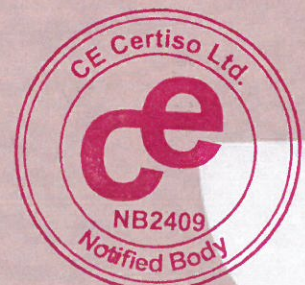
KE18G, KE19G, KE20G, KE22G, KE18GS, KE19GS, KE20GS

Issue: 1

Issued: 25 March 2021

CE Certiso
Orvos- és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 20147049-2-13


Valter PAPP, Dr.
General Manager



Declaration of Conformity

Revision 2

BALTON Sp. z o. o.**ul. Nowy Świat 7/14****00-496 Warszawa****POLAND****SRN: PL-MF-000010568**

declares under his sole responsibility that the products mentioned in the product list attached to this declaration are labelled with the CE safety mark. The granting of the mark is confirmed by certificates

Device	EC Certificate	EC Design Certificate
Anaesthesia sets	145084-21-03-25	145085-21-03-25

issued by the CE Certiso Ltd. certification body in Budakeszi, Hungary, bearing the identification mark of the notified body - 2409. These products conform the required technical documentation in accordance with the requirements of Annex II of the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and the amendment to Directive 2007/47/EC.

In addition, we declare that the distributed CE marked products, classified as Class III Rule 6, comply with the requirements of the applicable European Council Directive.

This declaration is supported by the Quality System developed base on the harmonized standards:

- EN ISO 13485:2016, Certificate no. SX 1023580-1 Notified Body TÜV Rheinland LGA Products GmbH.

This declaration of conformity is valid for all products bearing the CE mark and manufactured in the locations listed below:

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

PRODUCT LIST

Products included in the list below are covered by the Declaration of Conformity no RA/24/2022. All CE-marked products included in the list will be distributed by BALTON Sp. z o. o. in accordance with the provisions of the European Council Directive 93/42/EEC of 14.06.1993 concerning medical devices and the amendment to the Directive 2007/47/EC.

The list identifies products by name and model and Basic UDI-DI.

Product type according CE certificate and intended purpose	Type	Model	References	EMDN	Basic UDI-DI
Anaesthesia sets / Epidural anaesthesia sets are intended for the introduction of analgetic agents or opiate	Epidural anaesthesia set small	ZZOMA, ZZOMAS, ZZOMASN, ZZOMASSN, ZZOMAEM, ZZOMASEM, ZZOMASNEM, ZZOMASSNE, Where A - Size (16G; 17G; 18G; 19G) S – Soft tip SN – Low resistance syringe EM - Catheter fixing element	According to the Annex I	A01030103 / COMBINED EPIDURAL AND SPINAL ANAESTHESIA NEEDLES AND KITS	5901297ANAE STHESIA SETSYK
	Epidural anaesthesia set advanced	ZZORA, ZZORAS, ZZORAEM, ZZORASEM Where A - Size (16G; 17G; 18G; 19G) S - Soft tip EM - Catheter fixing element	According to the Annex II		
	Combined anaesthesia set advanced	ZZORAIB, ZZORASIB ZZORAIBEM, ZZORASIBEM Where A - Size (16G; 18G) S - Soft tip B – Spinal	According to the Annex III		

		needle size and length (IPPS26G / 130; IPPS 26G / 90; IPPW 26G / 90; IPPS 27G / 130; IPPS 27G / 120; IPPS 27G / 90; IPPW27G / 120; IPPW27G / 90; IPPS26G / 130; IPPS26G / 90; IPPW26G / 90; IPPS27G / 130; IPPS27G / 120; IPPS27G / 90; IPPW27G / 120; IPPW27G / 90)			
	Combined anaesthesia set small	ZZKA Where A - Size (16G; 18G)	According to the Annex IV		
	Epidural anaesthesia set with accessories for spinal and combined anaesthesia	ZZORAD, ZZORASD Where A - Size (18G; 19G; 20G; 22G) S – Soft tip D – Additional Elements (sterile field, bowl, gauze swab, tray, sponge, system for catheter fixing)	According to the Annex V		
	Tuohy needle	ITA Gdzie A - Size (16G; 17G; 18G; 19G)	According to the Annex VI	A01030102/ EPIDURAL ANAESTHESIA NEEDLES AND KITS	
	Epidural catheter	KEAS Where A - Size (18G; 19G; 20G; 22G) S - Soft tip	According to the Annex VII	N02010102/ PERIDURAL / EPIDURAL CATHETERS FOR CONTINUOUS ANALGESIA AND KITS	

19th April 2022
 Warsaw, Poland

A. Zajmowski-Olewno

Regulatory Affairs Director

J. Miodun

Person responsible for regulatory compliance

(PRRC)

ANNEX I - Epidural anaesthesia set small

ZZOM16G, ZZOM17G, ZZOM18G, ZZOM19G,
ZZOM16GS, ZZOM17GS, ZZOM18GS, ZZOM19GS,
ZZOM16GSN, ZZOM17GSN, ZZOM18GSN, ZZOM19GSN,
ZZOM16GSSN, ZZOM17GSSN, ZZOM18GSSN, ZZOM19GSSN,
ZZOM16GEM, ZZOM17GEM, ZZOM18GEM, ZZOM19GEM,
ZZOM16GSEM, ZZOM17GSEM, ZZOM18GSEM, ZZOM19GSEM,
ZZOM16GSNEM, ZZOM17GSNEM, ZZOM18GSNEM, ZZOM19GSNEM,
ZZOM16GSSNEM, ZZOM17GSSNEM, ZZOM18GSSNEM, ZZOM19GSSNEM.

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



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

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.

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