

# Certificate

## Quality Management System EN ISO 13485:2016


Registration No.: SX 1023580-1  
Certificate Holder: BALTON sp. z o.o.  
Nowy Świat 7/14  
00-496 Warszawa  
Poland

Scope: Design and development, production 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.

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.: 84970287-20  
Effective date: 2023-12-03  
Expiry date: 2026-12-02  
Issue date: 2023-12-03  
Replaces certificate SX 1023580-1 issued 2021-12-01

This certificate can be validated on <https://www.certipedia.com>

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

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Nowy Świat 7/14  
00-496 Warszawa  
Poland

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	BALTON sp. z o.o. 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, haemodialysis, radiology, cardiology, urology, anaesthesiology, gynaecology 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 Łajski Poland	Production of metal elements for medical devices. Provision of EO sterilization service according to EN ISO 11135:2014 standard.

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Daniel Świątko  
TÜV Rheinland LGA Products GmbH  
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## 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

<b>Device</b>	<b>EC Certificate</b>	<b>EC Design Certificate</b>
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 <b>A</b> - Size (16G; 17G; 18G; 19G) <b>S</b> – Soft tip SN – Low resistance syringe <b>EM</b> - Catheter fixing element	According to the Annex I	<b>A01030103 /</b> COMBINED EPIDURAL AND SPINAL ANAESTHESIA NEEDLES AND KITS	5901297ANAE STHESIA SETSYK
	Epidural anaesthesia set advanced	ZZORA, ZZORAS, ZZORAEM, ZZORASEM  Where <b>A</b> - Size (16G; 17G; 18G; 19G) <b>S</b> - Soft tip <b>EM</b> - Catheter fixing element	According to the Annex II		
	Combined anaesthesia set advanced	ZZORAIB, ZZORASIB ZZORAIBEM, ZZORASIBEM  Where <b>A</b> - Size (16G; 18G) <b>S</b> - Soft tip <b>B</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	

19<sup>th</sup> 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.



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## ANNEX II - Epidural anaesthesia set advanced

ZZOR16G, ZZOR17G, ZZOR18G, ZZOR19G,  
ZZOR16GS, ZZOR17GS, ZZOR18GS, ZZOR19GS,  
ZZOR16GEM, ZZOR17GEM, ZZOR18GEM, ZZOR19GEM,  
ZZOR16GSEM, ZZOR17GSEM, ZZOR18GSEM, ZZOR19GSEM.

**ANNEX III - Combined anaesthesia set advanced**

ZZOR16GSI26130, ZZOR16GSI2690, ZZOR16GSI2690W, ZZOR16GSI27130,  
ZZOR16GSI27120, ZZOR16GSI2790, ZZOR16GSI27120W, ZZOR16GSI2790W,

ZZOR18GSI26130, ZZOR18GSI2690, ZZOR18GSI2690W, ZZOR18GSI27130,  
ZZOR18GSI27120, ZZOR18GSI2790, ZZOR18GSI27120W, ZZOR18GSI2790W,

ZZOR16GI26130, ZZOR16GI2690, ZZOR16GI2690W, ZZOR16GI27130,  
ZZOR16GI27120, ZZOR16GI2790, ZZOR16GI27120W, ZZOR16GI2790W,

ZZOR18GI26130, ZZOR18GI2690, ZZOR18GI2690W, ZZOR18GI27130,  
ZZOR18GI27120, ZZOR18GI2790, ZZOR18GI27120W, ZZOR18GI2790W,

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





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**ANNEX IV - Combined anaesthesia set small**

ZZK16G, ZZK18G



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**ANNEX V - Epidural anaesthesia set with accessories for spinal and combined anaesthesia**

ZZOR16GD, ZZOR17GD, ZZOR18GD, ZZOR19GD,  
ZZOR16GSD, ZZOR17GSD, ZZOR18GSD, ZZOR19GSD



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## ANNEX VI – Tuohy Needle

IT16G, IT17G, IT18G, IT19G



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## ANNEX VII – Epidural catheter

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