ZARYS

product catalogue 2026

comprehensive solutions for healthcare providers

syringes

features
• syringes for subcutaneous, intramuscular and intravenous infusions intended for drawing up and administering of medicines/liquids to patient and collecting body fluid samples from patient

indication
• amber-coloured syringe is intended for drawing up and administering of photosensitive medicines

duoNEX
single-use syringe, 2-part, Luer

NEW

duoNEX

ref	type	capacity	position of nozzle	intermediate packaging	bulk packaging
002ML-2CZ-G	Luer	2 / 3 ml	centric	100 pcs	25 x 100 pcs
005ML-2CZ-G	Luer	5 / 6 ml	eccentric	100 pcs	15 x 100 pcs
010ML-2CZ-G	Luer	10 / 12 ml	eccentric	100 pcs	12 x 100 pcs
020ML-2CZ-G	Luer	20 / 24 ml	eccentric	100 pcs	8 x 100 pcs

STERILE EO · LATEX · PHT · 5 YEARS SHELF LIFE

packaging unit
1 pc. / paper-foil (blister)

dicoNEX SN
single-use syringe, 3-part, Luer, with needle alongside the syringe

dicoNEX SN

ref	type	capacity	needle size	position of nozzle	intermediate packaging	bulk packaging
002ML-3CZ-SN	Luer	2 / 2,2 ml	0,6 x 30 mm	centric	100 pcs	30 x 100 pcs
005ML-3CZ-SN	Luer	5 / 5,5 ml	0,7 x 30 mm	centric	100 pcs	24 x 100 pcs
010ML-3CZ-SN	Luer	10 / 11 ml	0,8 x 40 mm	centric	100 pcs	16 x 100 pcs
020ML-3CZ-SN	Luer	20 / 22 ml	0,8 x 40 mm	eccentric	50 pcs	16 x 50 pcs
050ML-3CZ-SN	Luer	50 / 60 ml	0,8 x 40 mm	eccentric	25 pcs	16 x 25 pcs

STERILE EO · LATEX · PHT · 5 YEARS SHELF LIFE

packaging unit
1 pc. / paper-foil (blister)

dicoNEX
single-use syringe, 3-part, Luer

dicoNEX

ref	type	capacity	position of nozzle	intermediate packaging	bulk packaging
001ML-3CZ-BL	Luer	1 ml	centric	100 pcs	24 x 100 pcs
002ML-3CZ-BL	Luer	2 ml	centric	100 pcs	30 x 100 pcs
005ML-3CZ-BL	Luer	5 ml	centric	100 pcs	24 x 100 pcs
010ML-3CZ-BL	Luer	10 ml	centric	100 pcs	16 x 100 pcs
020ML-3CZ-BL	Luer	20 ml	eccentric	50 pcs	16 x 50 pcs
050ML-3CZ-BL	Luer	50 / 60 ml	eccentric	25 pcs	16 x 25 pcs

STERILE EO · LATEX · PHT · 5 YEARS SHELF LIFE

packaging unit
1 pc. / paper-foil (blister)

dicoNEX
single-use syringe, 3-part, Luer-Lock + amber

dicoNEX

ref	type	capacity	position of nozzle	intermediate packaging	bulk packaging
003ML-3CZ-LL-BL	Luer-Lock	3 ml	centric	100 pcs	30 x 100 pcs
005ML-3CZ-LL-BL	Luer-Lock	5 ml	centric	100 pcs	24 x 100 pcs
010ML-3CZ-LL-BL	Luer-Lock	10 ml	centric	100 pcs	16 x 100 pcs
020ML-3CZ-LL-BL	Luer-Lock	20 ml	centric	50 pcs	16 x 50 pcs
030ML-3CZ-LL-BL	Luer-Lock	30 ml	centric	50 pcs	16 x 50 pcs
050ML-3CZ-LL-BL	Luer-Lock	50/60 ml	centric	25 pcs	16 x 25 pcs
050ML-3CZ-LL-B-BL	Luer-Lock	50/60 ml	centric	25 pcs	16 x 25 pcs

packaging unit
1 pc. / paper-foil

STERILE EO · LATEX · PHT · 5 YEARS SHELF LIFE

dicoNEX
single-use syringe, 3-part, Luer-Lock + amber

dicoNEX

ref	type	capacity	position of nozzle	intermediate packaging	bulk packaging
050ML-3CZ-LL-PI	Luer-Lock	50/60 ml	centric	25 pcs	16 x 25 pcs
050ML-3CZ-LL-B-PI	Luer-Lock	50/60 ml	centric	25 pcs	16 x 25 pcs

packaging unit
1 pc. / paper-foil

STERILE EO · LATEX · PHT · 5 YEARS SHELF LIFE

dicoNEX
single-use catheter syringe, 3-part

dicoNEX

ref	type	capacity	position of nozzle	intermediate packaging	bulk packaging
050ML-3CZ-CEW-BL	catheter tip	50/60 ml	centric	25 pcs	16 x 25 pcs
100ML-3CZ-CEW-BL	catheter tip	100 ml	centric	25 pcs	4 x 25 pcs

packaging unit
1 pc. / paper-foil

STERILE EO · LATEX · PHT · 5 YEARS SHELF LIFE

dicoTUBER
tuberculin syringe, Luer with needle alongside syringe

dicoTUBER

ref	type	capacity	needle size	no. of units
TU-U20-1-BL	Luer	1 ml	0,45 x 13 mm	20

indication
- 3-piece syringe intended for precise drawing up and administering of medicines/liquids

STERILE EO · LATEX · PHT · 5 YEARS SHELF LIFE

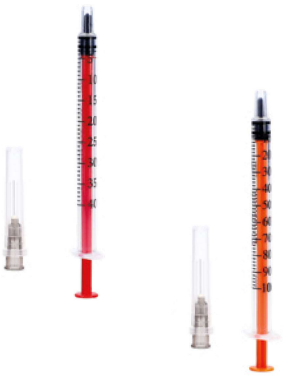
packaging unit
1 pc. / paper-foil (blister)

intermediate packaging
100 pcs

bulk packaging
32 x 100 pcs

dicoSULIN
insulin syringe, Luer with needle alongside the syringe

dicoSULIN



ref	type	capacity	needle size	no. of units
IN-U40-1-BL	Luer	1 ml	0,4 x 13 mm	40
IN-U100-1-BL	Luer	1 ml	0,4 x 13 mm	100

indication
- 3-piece syringe for subcutaneous, intramuscular and intravenous infusions
- for insulin shots

STERILE EO · LATEX · PHT · 5 YEARS SHELF LIFE

packaging unit
1 pc. / paper-foil (blister)

intermediate packaging
100 pcs

bulk packaging
32 x 100 pcs

thermPAD
cold/warm compress

ref	size	bulk packaging
KCZ7513	7,5 x 13 cm	100 x 1 pc.
KCZ7552	7,5 x 52 cm	30 x 1 pc.
KCZ1229	12 x 29 cm	25 x 1 pc.
KCZ1314	13 x 14 cm	50 x 1 pc.
KCZ1626	16 x 26 cm	20 x 1 pc.
KCZ2138	21 x 38 cm	10 x 1 pc.
KCZ3040	30 x 40 cm	8 x 1 pc.

resuable

packaging unit
1 pc. / foil bag

indication
- device used for the local cooling or heating of specific areas of the body to combat pain/neuralgia and reduce swelling and puffiness

NON STERILE · LATEX · PHT · 5 YEARS SHELF LIFE

gynPAD
gynaecological-maternity pad

ref	size
PG34090	34 cm x 9 cm

can be sterilised with ethylene oxide

NON STERILE · LATEX · PHT · 5 YEARS SHELF LIFE

packaging unit
10 x 1 pc.

bulk packaging
10 x 50 pcs

Alcohol Prep Pad
gauze pad moistened with alcohol

ref	size	no of plies
P1-IA-2	30 mm x 65 mm (unfolded) 30 mm x 32,5 mm (folded)	2
P2-IA-1	65 mm x 56 mm (unfolded) 32,5 mm x 28 mm (folded)	2
P2-IA-2	110 mm x 90 mm (unfolded) 55 mm x 45 mm (folded)	2

made of non-woven

soaked with isopropyl alcohol (70%)

indication
- disinfection of small surfaces

STERILE R · LATEX · PHT · 5 YEARS SHELF LIFE

packaging unit
2 x 1 pc. / paper-aluminum foil

bulk packaging
100 x 1 pc.
(50 x 2 pcs)

thermCARE
rescue blanket, foil, termic

ref	size
KR160210	160 cm x 210 cm

indication
- protection against hypothermia and overheating of the victim's body
- in emergency cases such as car accidents, ski accidents, in mountain tourism, in sport

NON STERILE · LATEX · PHT · 5 YEARS SHELF LIFE

packaging unit
1 pc. / zipper pouch

intermediate packaging
12 x 1 pc.

bulk packaging
20 x 12 pcs

EC Certificate

TÜVRheinland®

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.:	DD 1023663-1
Manufacturer:	ZARYS International Group Spółka z ograniczoną odpowiedzialnością, spółka komandytowa ul. Pod Borem 18 41-808 Zabrze Poland
Products:	- Sterile and non-sterile cutting gauze - Non-sterile dressing gauze - Sterile and non-sterile gauze swabs (with or without X-ray thread) - Sterile and non-sterile gauze lap sponges (with X-ray thread/ with X-ray chip) - Sterile and non-sterile gauze balls (with or without X-ray thread) - Sterile and non-sterile gauze rolls (with or without X-ray thread) - Sterile and non-sterile non-woven swabs (with or without X-ray thread) - Sterile paraffin gauze dressings - Sterile three-way stopcocks - Sterile transfusion sets for single use - Sterile infusion sets for single use - Sterile extension tubes for infusion pump - Sterile endotracheal tubes - Sterile tracheostomy tubes

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.:	84951712-170
Effective date:	2021-05-14
Expiry date:	2024-05-26
Issue date:	2021-05-14

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

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer:
ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

- Sterile breathing circuits
- Sterile catheter mounts
- Non-sterile anaesthetic masks
- Sterile laryngeal masks
- Sterile oxygen masks
- Sterile Venturi masks
- Sterile non-rebreath masks
- Sterile nebulizer masks
- Sterile nasal oxygen cannulas
- Sterile nebulizers
- Sterile oxygen tubing
- Sterile suction catheters
- Sterile abdominal drains
- Sterile feeding tubes
- Sterile stomach and duodenal tubes
- Sterile urology catheters
- Sterile surgical suction sets
- Sterile surgical suction cannulas
- Sterile syringes for single use
- Sterile insulin syringes
- Sterile tuberculin syringes
- Sterile hypodermic needles

Report No.: 84951712-170

Effective date: 2021-05-14

Expiry date: 2024-05-26

Issue date: 2021-05-14

TÜV Rheinland LGA Products GmbH Prüfstelle

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

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer:
ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

- Sterile insulin pen needles
- Sterile blood lancets
- Sterile IV cannulas
- Sterile needle free valves
- Sterile surgical gloves
- Sterile procedure kits

For the following medical devices the scope covers only the aspects of the manufacture concerned with securing and maintaining sterile conditions:

- Elastic bandages
- Adhesive cannula fixation dressings
- Adhesive wound dressings
- Eye pads
- Incise films
- Transparent film dressings
- Foam dressings
- Alginate dressings
- Absorbent wound dressings
- Surgical gowns
- Surgical drapes
- Sets of surgical drapes

Report No.: 84951712-170

Effective date: 2021-05-14

Expiry date: 2024-05-26

Issue date: 2021-05-14

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer:

ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

- Fluid collection pouches
- Nelaton catheters
- Vaginal speculums
- Cervical brushes
- Urine bags
- Enema bags
- Tongue depressors
- Oropharyngeal airways
- Intubation stylets
- Endotracheal tube holders
- Suction tubes
- Withdrawal cannulas
- Cannula stoppers
- Umbilical cord clamps

Replaces EC Certificate, Registration No.: DD 60139535 0001

Report No.: 84951712-170

Effective date: 2021-05-14

Expiry date: 2024-05-26

Issue date: 2021-05-14

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Prüfstelle

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TÜV Rheinland LGA Products GmbH
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer:
ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	ZARYS International Group Spółka z o.o. sp.k. ul. Pod Borem 18 41-808 Zabrze Poland	Activity: Final inspection and release.
/02	ZARYS International Group Spółka z o.o. sp.k ul. Guido Henckela Donnersmarcka 1 41-808 Zabrze Poland	Activity: Final inspection and release.

Report No.: 84951712-170

Effective date: 2021-05-14

Expiry date: 2024-05-26

Issue date: 2021-05-14

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Daniel Świątko
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

ZARYS International Group spółka z ograniczoną odpowiedzialnością spółka komandytowa
ul. Pod Borem 18,
41-808 Zabrze,
Poland

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date October 22, 2025

Notified Body Confirmation Letter
Reference. : ZARYS_PLA0_HZ_2024-05-10 replaced by
ZARYS_PLA0_HZ_2024-05-24 replaced by
ZARYS_PLA0_HZ_2025-02-07 replaced by
ZARYS_PLA0_HZ_2025-02-12 replaced by
ZARYS_PLA0_HZ_2025-10-15
/ 84965323

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

ZARYS International Group spółka z ograniczoną odpowiedzialnością spółka komandytowa
ul. Pod Borem 18,
41-808 Zabrze,
Poland
SRN Number: PL-MF-000000410

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity

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assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Elektronicznie podpisany przez Malgorzata Blazniak
Data: 2025.10.22 13:48:00 +02'00'

AUDIT_CERT_REVIEW
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
GAZA lux S **Cutting gauze, sterile** **Basic UDI-DI:** **59079968M02010101-ERR**	Class IIa	GAZA lux S Cutting gauze, sterile	DD 1023663-1 NB 0197
GAZA lux S **Cutting gauze, sterile** **Basic UDI-DI:** **59079968M02010101-SSM**	Class IIa	GAZA lux S Cutting gauze, sterile	DD 1023663-1 NB 0197
GAZA lux **Cutting gauze, non-sterile** **Basic UDI-DI:** **59079968M02010101-NSB**	Class IIa	GAZA lux Cutting gauze, non-sterile	DD 1023663-1 NB 0197
GAZA lux **Dressing gauze, non-sterile**	Class IIa	GAZA lux Dressing gauze, non-sterile	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 59079968M020107DG			
KOMPRI lux S Gauze swabs without X-ray thread, sterile **Basic UDI-DI: 59079968M02010201-ES4**	Class IIa	KOMPRI lux S Gauze swabs without X-ray thread, sterile	DD 1023663-1 NB 0197
KOMPRI lux S Gauze swabs without X-ray thread, sterile **Basic UDI-DI: 59079968M02010201-SSY**	Class IIa	KOMPRI lux S Gauze swabs without X-ray thread, sterile	DD 1023663-1 NB 0197
KOMPRI lux S Gauze swabs with X-ray thread, sterile **Basic UDI-DI: 59079968M02010202-ES9**	Class IIa	KOMPRI lux S Gauze swabs with X-ray thread, sterile	DD 1023663-1 NB 0197
KOMPRI lux S Gauze swabs with X-ray thread, sterile **Basic UDI-DI: 59079968M02010202-ST5**	Class IIa	KOMPRI lux S Gauze swabs with X-ray thread, sterile	DD 1023663-1 NB 0197
KOMPRI lux Gauze swabs without X-ray thread, non-sterile **Basic UDI-DI: 59079968M02010201-NSN**	Class IIa	KOMPRI lux Gauze swabs without X-ray thread, non-sterile	DD 1023663-1 NB 0197
KOMPRI lux Gauze swabs with X-ray thread, non-sterile **Basic UDI-DI: 59079968M02010202-NST**	Class IIa	KOMPRI lux Gauze swabs with X-ray thread, non-sterile	DD 1023663-1 NB 0197
SERVI lux S Gauze lap sponges with X-ray thread, sterile **Basic UDI-DI: 59079968M02010302-ESL**	Class IIa	SERVI lux S Gauze lap sponges with X-ray thread, sterile	DD 1023663-1 NB 0197
SERVI lux S Gauze lap sponges with X-ray thread, sterile **Basic UDI-DI: 59079968M02010302-STG**	Class IIa	SERVI lux S Gauze lap sponges with X-ray thread, sterile	DD 1023663-1 NB 0197
SERVI lux S	Class IIa	SERVI lux S Gauze lap sponges with X-ray	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Gauze lap sponges with X-ray chip, pre-washed, sterile **Basic UDI-DI: 59079968M02010302-PE86**		chip, pre-washed, sterile	
SERVI lux S **Gauze lap sponges with X-ray chip, pre-washed, sterile** **Basic UDI-DI: 59079968M02010302-PS92**	Class IIa	SERVI lux S Gauze lap sponges with X-ray chip, pre-washed, sterile	DD 1023663-1 NB 0197
SERVI lux **Gauze lap sponges with X-ray thread, non-sterile** **Basic UDI-DI: 59079968M02010302-NT6**	Class IIa	SERVI lux Gauze lap sponges with X-ray thread, non-sterile	DD 1023663-1 NB 0197
SERVI lux **Gauze lap sponges with X-ray chip, pre-washed, non-sterile** **Basic UDI-DI: 59079968M02010302-PN8Q**	Class IIa	SERVI lux Gauze lap sponges with X-ray chip, pre-washed, non-sterile	DD 1023663-1 NB 0197
TUPFER lux S **Gauze balls without X-ray thread, sterile** **Basic UDI-DI: 59079968M02010501-ET5**	Class IIa	TUPFER lux S Gauze balls without X-ray thread, sterile	DD 1023663-1 NB 0197
TUPFER lux S **Gauze balls without X-ray thread, sterile** **Basic UDI-DI: 59079968M02010501-STZ**	Class IIa	TUPFER lux S Gauze balls without X-ray thread, sterile	DD 1023663-1 NB 0197
TUPFER lux S **Gauze balls with X-ray thread, sterile** **Basic UDI-DI: 59079968M02010502-ETA**	Class IIa	TUPFER lux S Gauze balls with X-ray thread, sterile	DD 1023663-1 NB 0197
TUPFER lux S **Gauze balls with X-ray thread, sterile** **Basic UDI-DI: 59079968M02010502-SU6**	Class IIa	TUPFER lux S Gauze balls with X-ray thread, sterile	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
TUPFER lux Gauze balls without X-ray thread, non-sterile Basic UDI-DI: 59079968M02010501-NTP	Class IIa	TUPFER lux Gauze balls without X-ray thread, non-sterile	DD 1023663-1 NB 0197
TUPFER lux Gauze balls with X-ray thread, non-sterile Basic UDI-DI: 59079968M02010502-NTU	Class IIa	TUPFER lux Gauze balls with X-ray thread, non-sterile	DD 1023663-1 NB 0197
SETON lux S Gauze rolls without X-ray thread, sterile Basic UDI-DI: 59079968M02010701-SUP	Class IIa	SETON lux S Gauze rolls without X-ray thread, sterile	DD 1023663-1 NB 0197
SETON lux S Gauze rolls with X-ray thread, sterile Basic UDI-DI: 59079968M02010702-ETY	Class IIa	SETON lux S Gauze rolls with X-ray thread, sterile	DD 1023663-1 NB 0197
SETON lux S Gauze rolls with X-ray thread, sterile Basic UDI-DI: 59079968M02010702-SUU	Class IIa	SETON lux S Gauze rolls with X-ray thread, sterile	DD 1023663-1 NB 0197
SETON lux Gauze rolls without X-ray thread, non-sterile Basic UDI-DI: 59079968M02010701-NUD	Class IIa	SETON lux Gauze rolls without X-ray thread, non-sterile	DD 1023663-1 NB 0197
SETON lux Gauze rolls with X-ray thread, non-sterile Basic UDI-DI: 59079968M02010702-NUJ	Class IIa	SETON lux Gauze rolls with X-ray thread, non-sterile	DD 1023663-1 NB 0197
NONVI lux S Non-woven swab, sterile Basic UDI-DI: 59079968M02020101-ESA	Class IIa	NONVI lux S Non-woven swabs, sterile	DD 1023663-1 NB 0197
NONVI lux S Non-woven swab, sterile Basic UDI-DI: 59079968M02020101-ST6	Class IIa	NONVI lux S Non-woven swabs, sterile	DD 1023663-1 NB 0197
NONVI lux S	Class IIa	NONVI lux S	DD 1023663-1

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Non-woven swabs with X-ray thread, sterile **Basic UDI-DI: 59079968M02020102-ESF**		Non-woven swabs with X-ray thread, sterile	NB 0197
NONVI lux S **Non-woven swabs with X-ray thread, sterile** **Basic UDI-DI: 59079968M02020102-STB**	Class IIa	NONVI lux S Non-woven swabs with X-ray thread, sterile	DD 1023663-1 NB 0197
NONVI lux **Non-woven swabs, non-sterile** **Basic UDI-DI: 59079968M02020101-NSU**	Class IIa	NONVI lux Non-woven swabs, non-sterile	DD 1023663-1 NB 0197
NONVI lux **Non-woven swabs with X-ray thread, non-sterile** **Basic UDI-DI: 59079968M02020102-NSZ**	Class IIa	NONVI lux Non-woven swabs with X-ray thread, non-sterile	DD 1023663-1 NB 0197
paraffiNET **Paraffin gauze dressing, sterile** **Basic UDI-DI: 59079968M020302DG**	Class IIa	paraffiNET Paraffin gauze dressing, sterile	DD 1023663-1 NB 0197
SANVIflon I.V. cannula **SANVIflon S I.V. cannula without injection port** **SANVIflon premium I.V. cannula** **SANVIflon premium S I.V. cannula without injection port** **SANVIflon safe Safety I.V. cannula** **Basic UDI-DI: 59079968C0101017F**	Class IIa	SANVIflon I.V. cannula SANVIflon S I.V. cannula without injection port SANVIflon premium I.V. cannula SANVIflon premium S I.V. cannula without injection port SANVIflon safe Safety I.V. cannula	DD 1023663-1 NB 0197
OXYGEN TUBING **Basic UDI-DI: 59079968R03010204LA**	Class IIa	OXYGEN TUBING	DD 1023663-1 NB 0197
NEBULIZER with T F/M adaptor, mouthpiece, corrugated tube and tubing	Class IIa	NEBULIZER with T F/M adaptor, mouthpiece, corrugated tube and tubing	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 59079968R030103-FMV5			
NEBULIZER mask with tubing **Basic UDI-DI: 59079968R030103-MMN**	Class IIa	NEBULIZER with mask and tubing	DD 1023663-1 NB 0197
OXYGEN MASK with tubing **Basic UDI-DI: 59079968R03010201L4**	Class IIa	OXYGEN MASK with tubing	DD 1023663-1 NB 0197
NON-REBREATHER MASK with tubing **Basic UDI-DI: 59079968R03010206LE**	Class IIa	NON-REBREATHER MASK with tubing	DD 1023663-1 NB 0197
VENTURI MASK with adjustable diluter and tubing **Basic UDI-DI: 59079968R03010202-AXK**	Class IIa	VENTURI MASK with adjustable diluter and tubing	DD 1023663-1 NB 0197
NASAL OXYGEN CANNULA for adults **NASAL OXYGEN CANNULA for children** **NASAL OXYGEN CANNULA for infants** **Basic UDI-DI: 59079968R03010203L8**	Class IIa	NASAL OXYGEN CANNULA for adults NASAL OXYGEN CANNULA for children NASAL OXYGEN CANNULA for infants	DD 1023663-1 NB 0197
SUCTION CATHETER **SUCTION CATHETER with frozen surface, phthalate-free** **SUCTION CATHETER IDEAL** **SUCTION CATHETER with vacuum control** **SUCTION CATHETER with vacuum control IDEAL** **Basic UDI-DI: 59079968R0501QP**	Class IIa	SUCTION CATHETER SUCTION CATHETER with frozen surface, phthalate-free SUCTION CATHETER IDEAL SUCTION CATHETER with vacuum control SUCTION CATHETER with vacuum control IDEAL	DD 1023663-1 NB 0197
Two-way Foley catheter with rubber valve (silicone-coated latex) **Basic UDI-DI: 59079968U010201-LRXH**	Class IIa	TWO-WAY FOLEY CATHETER with rubber valve	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Two-way Foley catheter with plastic valve (silicone-coated latex) **Basic UDI-DI: 59079968U010201-LPXD**	Class IIa	TWO-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197
Two-way Foley catheter with plastic valve (100% silicone, X-ray contrast) **Basic UDI-DI: 59079968U010201-SP6**	Class IIa	TWO-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197
Three-way Foley catheter with plastic valve (silicone-coated latex) **Basic UDI-DI: 59079968U010201-3LUV**	Class IIa	THREE-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197
Three-way Foley catheter with plastic valve (100% silicone, X-ray contrast) **Basic UDI-DI: 59079968U010201-3SVB**	Class IIa	THREE-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197
Two-way Foley catheter with plastic valve, Tiemann tip (silicone-coated latex) **Basic UDI-DI: 59079968U0102R6**	Class IIa	TWO-WAY FOLEY CATHETER with plastic valve, Tiemann tip	DD 1023663-1 NB 0197
TIEMANN CATHETER **Basic UDI-DI: 59079968U010106HB**	Class IIa	TIEMANN CATHETER	DD 1023663-1 NB 0197
PEZZER CATHETER **Basic UDI-DI: 59079968U010107HD**	Class IIa	PEZZER CATHETER	DD 1023663-1 NB 0197
FEEDING TUBE **Basic UDI-DI: 59079968G02020101BU**	Class IIa	FEEDING TUBE	DD 1023663-1 NB 0197
STOMACH TUBE DUODENAL TUBE **Basic UDI-DI: 59079968G020201A3**	Class IIa	STOMACH TUBE DUODENAL TUBE	DD 1023663-1 NB 0197
SUCTION CANNULA with suction control SUCTION CANNULA without suction control	Class IIa	SUCTION CANNULA with suction control	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Basic UDI-DI: 59079968A06010184		SUCTION CANNULA without suction control	
SUCTION CANNULA with suction control, ball tip **SUCTION CANNULA without suction control, ball tip** **Basic UDI-DI: 59079968A060101-BA2**	Class IIa	SUCTION CANNULA with suction control, ball tip SUCTION CANNULA without suction control, ball tip	DD 1023663-1 NB 0197
SURGICAL SUCTION SET with suction control, Yankauer tip **SURGICAL SUCTION SET without suction control, Yankauer tip** **Basic UDI-DI: 59079968A060101039F**	Class IIa	SURGICAL SUCTION SET with suction control, Yankauer tip SURGICAL SUCTION SET without suction control, Yankauer tip	DD 1023663-1 NB 0197
SURGICAL SUCTION SET with suction control, funnel-funnel cut-to-fit, Yankauer tip **SURGICAL SUCTION SET without suction control, funnel-funnel cut-to-fit, Yankauer tip** **Basic UDI-DI: 59079968A06010103-FFUC**	Class IIa	SURGICAL SUCTION SET with suction control, funnel-funnel cut-to-fit, Yankauer tip SURGICAL SUCTION SET without suction control, funnel-funnel cut-to-fit, Yankauer tip	DD 1023663-1 NB 0197
SURGICAL SUCTION SET with suction control, funnel-funnel cut-to-fit, ball tip **SURGICAL SUCTION SET without suction control, funnel-funnel cut-to-fit, ball tip** **Basic UDI-DI: 59079968A06010103-FFB6J**	Class IIa	SURGICAL SUCTION SET with suction control, funnel-funnel cut-to-fit, ball tip SURGICAL SUCTION SET without suction control, funnel-funnel cut-to-fit, ball tip	DD 1023663-1 NB 0197
SUCTION TUBE funnel-funnel **Basic UDI-DI: 59079968A060304-FFG4**	Class IIa	SUCTION TUBE funnel-funnel	DD 1023663-1 NB 0197
SUCTION TUBE funnel-funnel cut-to-fit	Class IIa	SUCTION TUBE funnel-funnel cut-to-fit	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 59079968A060304-FCFW			
SUCTION TUBE funnel-Kapkon **Basic UDI-DI: 59079968A060304-FKGE**	Class IIa	SUCTION TUBE funnel-Kapkon	DD 1023663-1 NB 0197
easyWAY Three-way stopcock **Basic UDI-DI: 59079968A0703KA**	Class IIa	easyWAY Three-way stopcock	DD 1023663-1 NB 0197
easyWAY L Three-way stopcock with extension **Basic UDI-DI: 59079968A0703-LA4**	Class IIa	easyWAY L Three-way stopcock with extension	DD 1023663-1 NB 0197
easyFLOW LINE Extension tube for infusion pump, phthalate-free **Basic UDI-DI: 59079968A03020178**	Class IIa	easyFLOW LINE Extension tube for infusion pump, phthalate-free	DD 1023663-1 NB 0197
easyFLOW LINE AMBER Extension tube for infusion pump, amber, phthalate-free **Basic UDI-DI: 59079968A030201-A8Q**	Class IIa	easyFLOW LINE AMBER Extension tube for infusion pump, amber, phthalate-free	DD 1023663-1 NB 0197
easyFLOW IS Infusion set easyFLOW IS ECO Infusion set **Basic UDI-DI: 59079968A03010103-PHT6H**	Class IIa	easyFLOW IS Infusion set easyFLOW IS ECO Infusion set	DD 1023663-1 NB 0197
easyFLOW IS Infusion set, phthalate-free easyFLOW IS ECO Infusion set, phthalate-free easyFLOW IS PREMIUM Infusion set, phthalate-free **Basic UDI-DI: 59079968A030101037U**	Class IIa	easyFLOW IS Infusion set, phthalate-free easyFLOW IS ECO Infusion set, phthalate-free easyFLOW IS PREMIUM Infusion set, phthalate-free	DD 1023663-1 NB 0197
easyFLOW IS SAFE Safety infusion set, phthalate-free	Class IIa	easyFLOW IS SAFE Safety	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
easyFLOW IS SAFE PREMIUM Safety infusion set, phthalate-free **Basic UDI-DI: 59079968A03010103-SG2**		infusion set, phthalate-free easyFLOW IS SAFE PREMIUM Safety infusion set, phthalate-free	
easyFLOW IS REG Infusion set with precision flow rate regulator, phthalate-free **Basic UDI-DI: 59079968A03010103-RFY**	Class IIa	easyFLOW IS REG Infusion set with precision flow rate regulator, phthalate-free	DD 1023663-1 NB 0197
easyFLOW IS AMBER Infusion set, amber, phthalate-free **Basic UDI-DI: 59079968A03010103-AEW**	Class IIa	easyFLOW IS AMBER Infusion set, amber, phthalate-free	DD 1023663-1 NB 0197
ENDOTRACHEAL TUBE UNCUFFED **Basic UDI-DI: 59079968R010301FQ**	Class IIa	ENDOTRACHEAL TUBE UNCUFFED	DD 1023663-1 NB 0197
ENDOTRACHEAL TUBE CUFFED **Basic UDI-DI: 59079968R010302FS**	Class IIa	ENDOTRACHEAL TUBE CUFFED	DD 1023663-1 NB 0197
REINFORCED ENDOTRACHEAL TUBE CUFFED WITH PRELOADED STYLET **Basic UDI-DI: 59079968R010302-RMF**	Class IIa	REINFORCED ENDOTRACHEAL TUBE CUFFED WITH PRELOADED STYLET	DD 1023663-1 NB 0197
BREATHING CIRCUIT FOR CHILDREN with bag, expandable, additional arm **BREATHING CIRCUIT FOR ADULTS with bag, expandable, additional arm** **Basic UDI-DI: 59079968R0201-BGG**	Class IIa	BREATHING CIRCUIT FOR CHILDREN with bag, expandable, additional arm BREATHING CIRCUIT FOR ADULTS with bag, expandable, additional arm	DD 1023663-1 NB 0197
BREATHING CIRCUIT FOR CHILDREN **BREATHING CIRCUIT FOR ADULTS**	Class IIa	BREATHING CIRCUIT FOR CHILDREN BREATHING CIRCUIT FOR ADULTS	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 59079968R0201Q8			
CATHETER MOUNT with double swivel elbow connector, smooth-bore **Basic UDI-DI: 59079968R020202-SMP**	Class IIa	CATHETER MOUNT with double swivel elbow connector, smooth-bore	DD 1023663-1 NB 0197
CATHETER MOUNT with double swivel elbow connector, expandable **Basic UDI-DI: 59079968R020202-ELT**	Class IIa	CATHETER MOUNT with double swivel elbow connector, expandable	DD 1023663-1 NB 0197
CATHETER MOUNT with double swivel elbow connector, corrugated **Basic UDI-DI: 59079968R020202-CLP**	Class IIa	CATHETER MOUNT with double swivel elbow connector, corrugated	DD 1023663-1 NB 0197
CATHETER MOUNT with straight connector, smooth-bore **Basic UDI-DI: 59079968R020201-SMJ**	Class IIa	CATHETER MOUNT with straight connector, smooth-bore	DD 1023663-1 NB 0197
CATHETER MOUNT with straight connector, corrugated **Basic UDI-DI: 59079968R020201-CLJ**	Class IIa	CATHETER MOUNT with straight connector, corrugated	DD 1023663-1 NB 0197
CATHETER MOUNT with straight connector, expandable **Basic UDI-DI: 59079968R020201-ELN**	Class IIa	CATHETER MOUNT with straight connector, expandable	DD 1023663-1 NB 0197
CATHETER MOUNT with elbow connector, smooth-bore **Basic UDI-DI: 59079968R0202-SHP**	Class IIa	CATHETER MOUNT with elbow connector, smooth-bore	DD 1023663-1 NB 0197
CATHETER MOUNT with elbow connector, corrugated **Basic UDI-DI: 59079968R0202-CGP**	Class IIa	CATHETER MOUNT with elbow connector, corrugated	DD 1023663-1 NB 0197
CATHETER MOUNT with elbow connector, expandable	Class IIa	CATHETER MOUNT with elbow	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 59079968R0202-EGT		connector, expandable	
TRACHEOSTOMY TUBE cuffed **Basic UDI-DI: 59079968R010502G4**	Class IIa	TRACHEOSTOMY TUBE cuffed	DD 1023663-1 NB 0197
TRACHEOSTOMY TUBE uncuffed **Basic UDI-DI: 59079968R010501G2**	Class IIa	TRACHEOSTOMY TUBE uncuffed	DD 1023663-1 NB 0197
LARYNGEAL MASK, PVC, disposable **Basic UDI-DI: 59079968R0102-PH6**	Class IIa	LARYNGEAL MASK, PVC, disposable	DD 1023663-1 NB 0197
LARYNGEAL MASK, silicone, disposable **Basic UDI-DI: 59079968R0102-SHC**	Class IIa	LARYNGEAL MASK, silicone, disposable	DD 1023663-1 NB 0197
AIR CUSHION ANAESTHETIC MASK **Basic UDI-DI: 59079968R030101-CLQ**	Class IIa	AIR CUSHION ANAESTHETIC MASK	DD 1023663-1 NB 0197
ANAESTHETIC MASK with open seal **Basic UDI-DI: 59079968R030101-OMG**	Class IIa	ANAESTHETIC MASK with open seal	DD 1023663-1 NB 0197
duoNEX **Single use syringe, 2-part** **Basic UDI-DI: 59079968A0201020101DK**	Class IIa	duoNEX Single use syringe, 2-part	DD 1023663-1 NB 0197
dicoNEX **Single use syringe, 3-part (luer)** **Basic UDI-DI: 59079968A0201020102DM**	Class IIa	dicoNEX Single use syringe, 3-part (luer)	DD 1023663-1 NB 0197
Apteczka ABC **Strzykawka 3-częściowa** **Basic UDI-DI: 59079968A0201020102DM**	Class IIa	Apteczka ABC Strzykawka 3-częściowa	DD 1023663-1 NB 0197
dicoNEX **Single use syringe, 3-part (luer lock)**	Class IIa	dicoNEX Single use syringe, 3-part (luer lock)	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Basic UDI-DI: 59079968A0201020201DQ			
dicoNEX Single use amber syringe, 3-part (luer lock) **Basic UDI-DI: 59079968A0201020201-AVY**	Class IIa	dicoNEX Single use amber syringe, 3-part (luer lock)	DD 1023663-1 NB 0197
dicoNEX Single use catheter syringe, 3-part **Basic UDI-DI: 59079968A020102037G**	Class IIa	dicoNEX Single use catheter syringe, 3-part	DD 1023663-1 NB 0197
dicoNEX MN Single use syringe, 3-piece with mounted needle (luer) **dicoNEX SN Single use syringe, 3-piece, with needle alongside the syringe (luer)** **Basic UDI-DI: 59079968A0201020102-IWA**	Class IIa	dicoNEX MN Single use syringe, 3-piece with mounted needle (luer) dicoNEX SN Single use syringe, 3-piece, with needle alongside the syringe (luer)	DD 1023663-1 NB 0197
dicoNEX MN Single use syringe, 3-piece with mounted needle (luer lock) **dicoNEX SN Single use syringe, 3-piece, with needle alongside the syringe (luer lock)** **Basic UDI-DI: 59079968A0201020201-IWG**	Class IIa	dicoNEX MN Single use syringe, 3-piece with mounted needle (luer lock) dicoNEX SN Single use syringe, 3-piece, with needle alongside the syringe (luer lock)	DD 1023663-1 NB 0197
dicoNEX MN Single use amber syringe, 3-piece with mounted needle (luer lock) **dicoNEX SN Single use amber syringe, 3-piece, with needle alongside the syringe (luer lock)** **Basic UDI-DI: 59079968A0201020201-IA9D**	Class IIa	dicoNEX MN Single use amber syringe, 3-piece with mounted needle (luer lock) dicoNEX SN Single use amber syringe, 3-piece, with needle alongside the syringe (luer lock)	DD 1023663-1 NB 0197
dicoSULIN Insulin syringe	Class IIa	dicoSULIN Insulin syringe	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Basic UDI-DI: 59079968A02010672			
dicoTUBER Tuberculin syringe **Basic UDI-DI: 59079968A02010978**	Class IIa	dicoTUBER Tuberculin syringe	DD 1023663-1 NB 0197
dispoFINE Injection needle **Basic UDI-DI: 59079968A0101010102CK**	Class IIa	dispoFINE Injection needle	DD 1023663-1 NB 0197
dispoGUARD Safety injection needle **Basic UDI-DI: 59079968A0101010101CH**	Class IIa	dispoGUARD Safety injection needle	DD 1023663-1 NB 0197
dispoSULIN Insulin pen needle **Basic UDI-DI: 59079968A010101026Q**	Class IIa	dispoSULIN Insulin pen needle	DD 1023663-1 NB 0197
easyFLOW TS Transfusion set **Basic UDI-DI: 59079968A03010102-PHT66**	Class IIa	easyFLOW TS Transfusion set	DD 1023663-1 NB 0197
easyFLOW TS Transfusion set, phthalate-free easyFLOW TS PREMIUM Transfusion set, phthalate-free **Basic UDI-DI: 59079968A030101027S**	Class IIa	easyFLOW TS Transfusion set, phthalate-free easyFLOW TS PREMIUM Transfusion set, phthalate-free	DD 1023663-1 NB 0197
NEEDLE FREE VALVE blue **Basic UDI-DI: 59079968A0705KE**	Class IIa	NEEDLE FREE VALVE blue	DD 1023663-1 NB 0197
NEEDLE FREE VALVE transparent **Basic UDI-DI: 59079968A07050295**	Class IIa	NEEDLE FREE VALVE transparent	DD 1023663-1 NB 0197
NEEDLE FREE VALVE transparent with extension line, single NEEDLE FREE VALVE transparent with extension line, double	Class IIa	NEEDLE FREE VALVE transparent with extension line, single NEEDLE FREE VALVE transparent	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NEEDLE FREE VALVE transparent with extension line, triple **NEEDLE FREE VALVE transparent with extension line, quadruple** **Basic UDI-DI: 59079968A070502-LCQ**		with extension line, double NEEDLE FREE VALVE transparent with extension line, triple NEEDLE FREE VALVE transparent with extension line, quadruple	
safeCARE Surgical gloves, latex, powdered, sterile **Basic UDI-DI: 59079968T01010101-RYM**	Class IIa	safeCARE Surgical gloves, latex, powdered, sterile	DD 1023663-1 NB 0197
safeCARE PF Surgical gloves, latex, powder free, sterile **Basic UDI-DI: 59079968T01010102-RYS**	Class IIa	safeCARE PF Surgical gloves, latex, powder free, sterile	DD 1023663-1 NB 0197
safeCARE basic Surgical gloves latex, powdered, sterile **Basic UDI-DI: 59079968T01010101-RYM**	Class IIa	safeCARE basic Surgical gloves latex, powdered, sterile	DD 1023663-1 NB 0197
safeCARE basic PF Surgical gloves latex, powder-free, sterile **Basic UDI-DI: 59079968T01010102-RYS**	Class IIa	safeCARE basic PF Surgical gloves latex, powder-free, sterile	DD 1023663-1 NB 0197
safeCARE premium Surgical gloves latex, powder-free, sterile **safeCARE UG Surgical gloves latex, powder-free, sterile** **safeCARE micro Surgical gloves latex, powder-free, sterile** **safeCARE ortho Surgical gloves latex, powder-free, sterile** **safeCARE dual Surgical gloves latex, powder-free, sterile** **Basic UDI-DI: 59079968T01010102-RYS**	Class IIa	safeCARE premium Surgical gloves latex, powder-free, sterile safeCARE UG Surgical gloves latex, powder-free, sterile safeCARE micro Surgical gloves latex, powder-free, sterile safeCARE ortho Surgical gloves latex, powder-free, sterile safeCARE dual Surgical gloves	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
		latex, powder-free, sterile	
safeCARE synthetic Surgical gloves neoprene, powder-free, sterile **safeCARE synthetic UG Surgical gloves neoprene, powder-free, sterile** **Basic UDI-DI: 59079968T010102-NRWL**	Class IIa	safeCARE synthetic Surgical gloves neoprene, powder-free, sterile safeCARE synthetic UG Surgical gloves neoprene, powder-free, sterile	DD 1023663-1 NB 0197
safeCARE fusion Surgical gloves polyisoprene, powder-free, sterile **Basic UDI-DI: 59079968T010102-PRWS**	Class IIa	safeCARE fusion Surgical gloves polyisoprene, powder-free, sterile	DD 1023663-1 NB 0197
safeCARE virtuo Surgical gloves flexylon, powder-free, sterile **safeCARE virtuo UG Surgical gloves flexylon, powder-free, sterile** **safeCARE pro protect Surgical gloves flexylon, powder-free, sterile** **Basic UDI-DI: 59079968T010102-FRVU**	Class IIa	safeCARE virtuo Surgical gloves flexylon, powder-free, sterile safeCARE virtuo UG Surgical gloves flexylon, powder-free, sterile safeCARE pro protect Surgical gloves flexylon, powder-free, sterile	DD 1023663-1 NB 0197
safeLANCE Pressure-activated safety lancet **Basic UDI-DI: 59079968V0104RM**	Class IIa	safeLANCE Pressure-activated safety lancet	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-SETA**	Class IIa	deltaset Urinary bladder catheterization kit	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-SHTG**	Class IIa	deltaset Urinary bladder catheterization kit	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-CERS**	Class IIa	deltaset Dialysis kit	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-CHRY**	Class IIa	deltaset Dialysis kit	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-WETN**	Class IIa	deltaset Dressing change kit	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-WHTU**	Class IIa	deltaset Dressing change kit	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-RET7**	Class IIa	deltaset Suture application kit deltaset Suture removal kit	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-RHTD**	Class IIa	deltaset Suture application kit deltaset Suture removal kit	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-IESC**	Class IIa	deltaset Anasthesia kit deltaset Puncture kit	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-IHSJ**	Class IIa	deltaset Anasthesia kit deltaset Puncture kit	DD 1023663-1 NB 0197
elastopor STERIL Non-woven dressing with absorbent pad, self-adhesive, sterile **elastoKIDS STERIL Non-woven dressing with absorbent pad, self-adhesive, sterile** **Basic UDI-DI: 59079968M040101-WJW**	Class I devices placed on the market in sterile condition	elastopor STERIL Non-woven dressing with absorbent pad, self-adhesive, sterile elastoKIDS STERIL Non-woven dressing with absorbent pad, self-adhesive, sterile	DD 1023663-1 NB 0197
elastoDERM PAD Foil dressing, with absorbent pad, self-adhesive, sterile	Class I devices placed on the market in sterile condition	elastoDERM PAD Foil dressing, with absorbent pad,	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 59079968M040101-FHU		self-adhesive, sterile	
elastoSTRIP Wound closure strips, sterile **Basic UDI-DI: 59079968M040499FL**	Class I devices placed on the market in sterile condition	elastoSTRIP Wound closure strips, sterile	DD 1023663-1 NB 0197
UMBILICAL CORD CLAMP, sterile **Basic UDI-DI: 59079968V0202RN**	Class I devices placed on the market in sterile condition	UMBILICAL CORD CLAMP, sterile	DD 1023663-1 NB 0197
ALPHAtex Procedure gown NORMAL, sterile **Basic UDI-DI: 59079968T0205R6**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown NORMAL, sterile	DD 1023663-1 NB 0197
ALPHAtex Procedure gown NORMAL-P **Basic UDI-DI: 59079968T0205R6**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown NORMAL-P, sterile	HD 1023663-1 NB 0197
ALPHAtex Surgical gown STANDARD, sterile **ALPHAtex Surgical gown COMFORT sterile** **Basic UDI-DI: 59079968T020401HA**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown STANDARD, sterile ALPHAtex Surgical gown COMFORT sterile	DD 1023663-1 NB 0197
ALPHAtex Surgical gown CLASSIC-P **ALPHAtex Surgical gown STANDARD-P** **ALPHAtex Surgical gown COMFORT-P** **Basic UDI-DI: 59079968T020401HA**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown CLASSIC-P, sterile ALPHAtex Surgical gown STANDARD-P, sterile ALPHAtex Surgical gown COMFORT-P sterile	HD 1023663-1 NB 0197
ALPHAtex Surgical gown STANDARD PLUS, with impermeable parts, sterile **ALPHAtex Surgical gown COMFORT PLUS, with impermeable parts, sterile** **ALPHAtex Surgical gown EXTRA SAFE, with impermeable parts, sterile**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown STANDARD PLUS, with impermeable parts, sterile ALPHAtex Surgical gown COMFORT PLUS, with impermeable parts, sterile ALPHAtex Surgical gown EXTRA SAFE, with	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 59079968T020402HC		impermeable parts, sterile	
ALPHAtex Surgical gown STANDARD PLUS-P, with impermeable parts **ALPHAtex Surgical gown COMFORT PLUS-P, with impermeable parts** **ALPHAtex Surgical gown EXTRA SAFE-P, with impermeable parts** **Basic UDI-DI: 59079968T020402HC**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown STANDARD PLUS-P, with impermeable parts, sterile ALPHAtex Surgical gown COMFORT PLUS-P, with impermeable parts, sterile ALPHAtex Surgical gown EXTRA SAFE-P, with impermeable parts, sterile	HD 1023663-1 NB 0197
ALPHAtex Surgical drape, sterile **ALPHAtex 2-layer surgical drape, with cellulose layer, sterile** **ALPHAtex 2-layer surgical drape, sterile** **ALPHAtex 2-layer surgical drape with adhesive edge, sterile** **ALPHAtex 2-layer surgical drape with central fenestration, sterile** **ALPHAtex 2-layer surgical drape with central adhesive fenestration, sterile** **ALPHAtex 2-layer surgical drape with central, adjustable adhesive fenestration, sterile** **ALPHAtex 2-layer epidural surgical drape with adhesive fenestration, sterile** **ALPHAtex 3-layer surgical drape, sterile** **ALPHAtex 3-layer surgical drape with adhesive edge, sterile** **ALPHAtex 3-layer surgical drape with**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical drape, sterile ALPHAtex 2-layer surgical drape, with cellulose layer, sterile ALPHAtex 2-layer surgical drape, sterile ALPHAtex 2-layer surgical drape with adhesive edge, sterile ALPHAtex 2-layer surgical drape with central fenestration, sterile ALPHAtex 2-layer surgical drape with central adhesive fenestration, sterile ALPHAtex 2-layer surgical drape with central, adjustable adhesive fenestration, sterile ALPHAtex 2-layer epidural surgical drape with adhesive fenestration, sterile ALPHAtex 3-layer surgical drape, sterile	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
central fenestration, sterile **ALPHAtex 3-layer surgical drape with central adhesive fenestration, sterile** **ALPHAtex Reinforced surgical drape with adhesive fenestration, sterile** **Basic UDI-DI: 59079968T0201QW**		ALPHAtex 3-layer surgical drape with adhesive edge, sterile ALPHAtex 3-layer surgical drape with central fenestration, sterile ALPHAtex 3-layer surgical drape with central adhesive fenestration, sterile ALPHAtex Reinforced surgical drape with adhesive fenestration, sterile	
ALPHAtex Surgical drape **ALPHAtex 2-layer surgical drape, with cellulose layer** **ALPHAtex 2-layer surgical drape** **ALPHAtex 2-layer surgical drape with adhesive edge** **ALPHAtex 2-layer surgical drape with central fenestration** **ALPHAtex 2-layer surgical drape with central adhesive fenestration** **ALPHAtex 3-layer surgical drape** **ALPHAtex 3-layer surgical drape with adhesive edge** **ALPHAtex 3-layer surgical drape with central fenestration** **ALPHAtex 3-layer surgical drape with central adhesive fenestration** **Basic UDI-DI: 59079968T0201QW**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical drape, sterile ALPHAtex 2-layer surgical drape, with cellulose layer, sterile ALPHAtex 2-layer surgical drape, sterile ALPHAtex 2-layer surgical drape with adhesive edge, sterile ALPHAtex 2-layer surgical drape with central fenestration, sterile ALPHAtex 2-layer epidural surgical drape with adhesive fenestration, sterile ALPHAtex 3-layer surgical drape, sterile ALPHAtex 3-layer surgical drape with adhesive edge, sterile ALPHAtex 3-layer surgical drape with central fenestration, sterile ALPHAtex 3-layer surgical drape with	HD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
		central adhesive fenestration, sterile	
ALPHAtex Instrument table cover, sterile **Basic UDI-DI: 59079968T030101-INJ**	Class I devices placed on the market in sterile condition	ALPHAtex Instrument table cover, sterile	DD 1023663-1 NB 0197
ALPHAtex Reinforced Mayo stand cover, sterile **ALPHAtex Reinforced Mayo stand cover, red, sterile** **Basic UDI-DI: 59079968T030101-MNS**	Class I devices placed on the market in sterile condition	ALPHAtex Reinforced Mayo stand cover, sterile ALPHAtex Reinforced Mayo stand cover, red, sterile	DD 1023663-1 NB 0197
ALPHAtex Armboard cover, sterile **ALPHAtex Surgical pocket for syringes, sterile** **Basic UDI-DI: 59079968T030101-NNU**	Class I devices placed on the market in sterile condition	ALPHAtex Armboard cover, sterile ALPHAtex Surgical pocket for syringes, sterile	DD 1023663-1 NB 0197
ALPHAtex Camera cables cover, sterile **ALPHAtex Circular banded cover for medical devices, sterile** **ALPHAtex Square banded cover for medical devices, sterile** **ALPHAtex C-arm cover set, sterile** **ALPHAtex Lamp handle cover, sterile** **ALPHAtex Ultrasound cover kits, sterile** **Basic UDI-DI: 59079968T030101-FNC**	Class I devices placed on the market in sterile condition	ALPHAtex Camera cables cover, sterile ALPHAtex Circular banded cover for medical devices, sterile ALPHAtex Square banded cover for medical devices, sterile ALPHAtex C-arm cover set, sterile ALPHAtex Lamp handle cover, sterile ALPHAtex Ultrasound cover kits, sterile	DD 1023663-1 NB 0197
ALPHAtex Absorbent drape, sterile **ALPHAtex Absorbent drape for newborn, sterile** **Basic UDI-DI: 59079968T020199-SRU**	Class I devices placed on the market in sterile condition	ALPHAtex Absorbent drape, sterile ALPHAtex Absorbent drape for newborn, sterile	DD 1023663-1 NB 0197
ALPHAtex Absorbent drape, sterile	Class I devices placed on the	ALPHAtex Absorbent drape, sterile	HD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
ALPHAtex Absorbent drape for newborn, sterile **Basic UDI-DI: 59079968T020199-SRU**	market in sterile condition	ALPHAtex Absorbent drape for newborn, sterile	
ALPHAtex Limb cover, sterile **ALPHAtex Head Turban drape, sterile** **ALPHAtex Under buttocks drape, sterile** **Basic UDI-DI: 59079968T020102GV**	Class I devices placed on the market in sterile condition	ALPHAtex Limb cover, sterile ALPHAtex Head Turban drape, sterile ALPHAtex Under buttocks drape, sterile	DD 1023663-1 NB 0197
ALPHAtex Adhesive pouch, one-chamber, sterile **ALPHAtex Adhesive pouch, two-chamber, sterile** **ALPHAtex Adhesive pouch, three-chamber, sterile** **ALPHAtex Arthroscopy fluid collection pouch, cone-shaped, with outlet tip, sterile** **ALPHAtex Fluid collection pouch, cone-shaped, with outlet tip, sterile** **Basic UDI-DI: 59079968T020199-PRN**	Class I devices placed on the market in sterile condition	ALPHAtex Adhesive pouch, one-chamber, sterile ALPHAtex Adhesive pouch, two-chamber, sterile ALPHAtex Arthroscopy fluid collection pouch, cone-shaped, with outlet tip, sterile ALPHAtex Fluid collection pouch, cone-shaped, with outlet tip, sterile	DD 1023663-1 NB 0197
ALPHAtex Non-woven surgical tape, adhesive, sterile **ALPHAtex Velcro surgical tape, sterile** **Basic UDI-DI: 59079968T020199-TRW**	Class I devices placed on the market in sterile condition	ALPHAtex Non-woven surgical tape, adhesive, sterile ALPHAtex Velcro surgical tape, sterile	DD 1023663-1 NB 0197
ALPHAtex Abdominal drape, sterile **ALPHAtex Abdo-Perineal drape, sterile** **ALPHAtex Angiography drape, sterile** **ALPHAtex Cardiology drape, sterile** **ALPHAtex Cardiac drape, sterile**	Class I devices placed on the market in sterile condition	ALPHAtex Abdominal drape, sterile ALPHAtex Abdo-Perineal drape, sterile ALPHAtex Angiography drape, sterile	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
ALPHAtex C-section drape, sterile **ALPHAtex Delivery drape, sterile** **ALPHAtex Extremity drape, sterile** **ALPHAtex Gynaecology drape, sterile** **ALPHAtex Laparoscopy drape, sterile** **ALPHAtex Ophthalmic drape, sterile** **ALPHAtex Orthopaedic drape, sterile** **ALPHAtex Shoulder drape, sterile** **ALPHAtex Vertical isolation drape, sterile** **Basic UDI-DI: 59079968T0202QY**		ALPHAtex Cardiology drape, sterile ALPHAtex Cardiac drape, sterile ALPHAtex C-section drape, sterile ALPHAtex Delivery drape, sterile ALPHAtex Extremity drape, sterile ALPHAtex Gynaecology drape, sterile ALPHAtex Laparoscopy drape, sterile ALPHAtex Ophthalmic drape, sterile ALPHAtex Orthopaedic drape, sterile ALPHAtex Shoulder drape, sterile ALPHAtex Vertical isolation drape, sterile	
ALPHAtex Abdominal drape, sterile **ALPHAtex Abdo-Perineal drape, sterile** **ALPHAtex Angiography drape, sterile** **ALPHAtex Cardiology drape, sterile** **ALPHAtex Cardiac drape, sterile** **ALPHAtex C-section drape, sterile** **ALPHAtex Delivery drape, sterile** **ALPHAtex Extremity drape, sterile** **ALPHAtex Gynaecology drape, sterile** **ALPHAtex Laparoscopy drape, sterile** **ALPHAtex Ophthalmic drape, sterile**	Class I devices placed on the market in sterile condition	ALPHAtex Abdominal drape (from 1 to 100) ALPHAtex Abdo-Perineal drape (from 1 to 100) ALPHAtex Angiography drape (from 1 to 100) ALPHAtex Cardiology drape (from 1 to 100) ALPHAtex Cardiac drape (from 1 to 100) ALPHAtex C-section drape (from 1 to 100) ALPHAtex Delivery drape (from 1 to 100)	HD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ALPHAtex Orthopaedic drape, sterile **ALPHAtex Shoulder drape, sterile** **ALPHAtex Vertical isolation drape, sterile** **Basic UDI-DI: 59079968T0202QY**		ALPHAtex Extremity drape (from 1 to 100) ALPHAtex Gynaecology drape (from 1 to 100) ALPHAtex Laparoscopy drape (from 1 to 100) ALPHAtex Ophthalmic drape (from 1 to 100) ALPHAtex Orthopaedic drape (from 1 to 100) ALPHAtex Shoulder drape (from 1 to 100) ALPHAtex Vertical isolation drape (from 1 to 100)	
ALPHAtex Abdominal set, sterile **ALPHAtex Abdo-Perineal set, sterile** **ALPHAtex Ablation set, sterile** **ALPHAtex Angiography set, sterile** **ALPHAtex Arthroscopy set, sterile** **ALPHAtex Basic set, sterile** **ALPHAtex Cardiology set, sterile** **ALPHAtex Cardiac set, sterile** **ALPHAtex Craniotomy set, sterile** **ALPHAtex C-section set, sterile** **ALPHAtex Cystoscopy set, sterile** **ALPHAtex Delivery set, sterile** **ALPHAtex Dental set, sterile** **ALPHAtex Dynamic hip screw set, sterile** **ALPHAtex Extremity set, sterile**	Class I devices placed on the market in sterile condition	ALPHAtex Abdominal set, sterile ALPHAtex Abdo-Perineal set, sterile ALPHAtex Ablation set, sterile ALPHAtex Angiography set, sterile ALPHAtex Arthroscopy set, sterile ALPHAtex Basic set, sterile ALPHAtex Cardiology set, sterile ALPHAtex Cardiac set, sterile ALPHAtex Craniotomy set, sterile ALPHAtex C-section set, sterile ALPHAtex Cystoscopy set, sterile ALPHAtex Delivery set, sterile	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
ALPHAtex Gynaecology set, sterile **ALPHAtex Hip set, sterile** **ALPHAtex Laparoscopy set, sterile** **ALPHAtex Laryngology set, sterile** **ALPHAtex Ophthalmic set, sterile** **ALPHAtex Otolaryngology set, sterile** **ALPHAtex Pediatric set, sterile** **ALPHAtex Percutaneous lithotripsy set, sterile** **ALPHAtex Shoulder set, sterile** **ALPHAtex Spine set, sterile** **ALPHAtex Thyroid set, sterile** **ALPHAtex TUR set, sterile** **ALPHAtex Universal set, sterile** **ALPHAtex Uro/gynaecology set, sterile** **ALPHAtex Varicose vein set, sterile** **ALPHAtex Vertical isolation set, sterile** **Basic UDI-DI: 59079968T0202QY**		ALPHAtex Dental set, sterile ALPHAtex Dynamic hip screw set, sterile ALPHAtex Extremity set, sterile ALPHAtex Gynaecology set, sterile ALPHAtex Hip set, sterile ALPHAtex Laparoscopy set, sterile ALPHAtex Laryngology set, sterile ALPHAtex Ophthalmic set, sterile ALPHAtex Otolaryngology set, sterile ALPHAtex Pediatric set, sterile ALPHAtex Percutaneous lithotripsy set, sterile ALPHAtex Shoulder set, sterile ALPHAtex Spine set, sterile ALPHAtex Thyroid set, sterile ALPHAtex TUR set, sterile ALPHAtex Universal set, sterile ALPHAtex Uro/gynaecology set, sterile ALPHAtex Varicose vein set, sterile ALPHAtex Vertical isolation set, sterile	

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ALPHAtex Abdominal set, sterile **ALPHAtex Abdo-Perineal set, sterile** **ALPHAtex Ablation set, sterile** **ALPHAtex Angiography set, sterile** **ALPHAtex Arthroscopy set, sterile** **ALPHAtex Basic set, sterile** **ALPHAtex Cardiology set, sterile** **ALPHAtex Cardiac set, sterile** **ALPHAtex Craniotomy set, sterile** **ALPHAtex C-section set, sterile** **ALPHAtex Cystoscopy set, sterile** **ALPHAtex Delivery set, sterile** **ALPHAtex Dental set, sterile** **ALPHAtex Dynamic hip screw set, sterile** **ALPHAtex Extremity set, sterile** **ALPHAtex Gynaecology set, sterile** **ALPHAtex Hip set, sterile** **ALPHAtex Laparoscopy set, sterile** **ALPHAtex Laryngology set, sterile** **ALPHAtex Ophthalmic set, sterile** **ALPHAtex Otolaryngology set, sterile** **ALPHAtex Pediatric set, sterile** **ALPHAtex Percutaneous lithotripsy set, sterile** **ALPHAtex Shoulder set, sterile** **ALPHAtex Spine set, sterile** **ALPHAtex Thyroid set, sterile**	Class I devices placed on the market in sterile condition	"ALPHAtex Abdominal set (from 1 to 200) ALPHAtex Abdo-Perineal set (from 1 to 200) ALPHAtex Ablation set (from 1 to 200) ALPHAtex Angiography set (from 1 to 200) ALPHAtex Arthroscopy set (from 1 to 200) ALPHAtex Basic set (from 1 to 200) ALPHAtex Cardiology set (from 1 to 200) ALPHAtex Cardiac set (from 1 to 200) ALPHAtex Craniotomy set (from 1 to 200) ALPHAtex C-section set (from 1 to 200) ALPHAtex Cystoscopy set (from 1 to 200) ALPHAtex Delivery set (from 1 to 200) ALPHAtex Dental set (from 1 to 200) ALPHAtex Dynamic hip screw set (from 1 to 200) ALPHAtex Extremity set (from 1 to 200) ALPHAtex Gynaecology set (from 1 to 200) ALPHAtex Hip set (from 1 to 200) ALPHAtex Laparoscopy set (from 1 to 200) ALPHAtex Laryngology set (from 1 to 200)	HD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ALPHAtex TUR set, sterile **ALPHAtex Universal set, sterile** **ALPHAtex Uro/gynaecology set, sterile** **ALPHAtex Varicose vein set, sterile** **ALPHAtex Vertical isolation set, sterile** **Basic UDI-DI: 59079968T0202QY**		ALPHAtex Ophthalmic set (from 1 to 200) ALPHAtex Otolaryngology set (from 1 to 200) ALPHAtex Pediatric set (from 1 to 200) ALPHAtex Percutaneous lithotripsy set (from 1 to 200) ALPHAtex Shoulder set (from 1 to 200) ALPHAtex Spine set (from 1 to 200) ALPHAtex Thyroid set (from 1 to 200) ALPHAtex TUR set (from 1 to 200) ALPHAtex Universal set (from 1 to 200) ALPHAtex Uro/gynaecology set (from 1 to 200) ALPHAtex Varicose vein set (from 1 to 200) ALPHAtex Vertical isolation set (from 1 to 200)"	
elastoLUMENAL S Eye pad, superabsorbent, multi-layer, sterile **Basic UDI-DI: 59079968M040301-SKC**	Class I devices placed on the market in sterile condition	elastoLUMENAL S Eye pad, superabsorbent, multi-layer, sterile	DD 1023663-1 NB 0197
elastopor EYE Eye dressing, non-woven, with absorbent pad, self-adhesive, sterile **elastoKIDS EYE Eye dressing, non-woven, with absorbent pad, self-adhesive, sterile** **Basic UDI-DI: 59079968M0403NX**	Class I devices placed on the market in sterile condition	lastopor EYE Eye dressing, non-woven, with absorbent pad, self-adhesive, sterile elastoKIDS EYE Eye dressing, non-woven, with absorbent pad,	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
		self-adhesive, sterile	
COMBI STOPPER **Basic UDI-DI: 59079968C01018085**	Class I devices placed on the market in sterile condition	COMBI STOPPER	DD 1023663-1 NB 0197
LUER LOCK STOPPER **Basic UDI-DI: 59079968C01018085**	Class I devices placed on the market in sterile condition	LUER LOCK STOPPER	DD 1023663-1 NB 0197
elastopor STERIL D Non-woven dressing with absorbent pad, with incision and O-hole, self-adhesive, sterile **elastoKIDS STERIL D Non-woven dressing, with absorbent pad, with incision and X-hole, self-adhesive, sterile** **Basic UDI-DI: 59079968M04010201-DTG**	Class I devices placed on the market in sterile condition	elastopor STERIL D Non-woven dressing with absorbent pad, with incision and O-hole, self-adhesive, sterile elastopor STERIL D Non-woven dressing, with absorbent pad, with incision and X-hole, self-adhesive, sterile elastoKIDS STERIL D Non-woven dressing, with absorbent pad, with incision and X-hole, self-adhesive, sterile	DD 1023663-1 NB 0197
NONVI lux S Non-woven swab, with O-incision, sterile **NONVI lux S Non-woven swab, with Y-incision, sterile** **Basic UDI-DI: 59079968M04010201-NU4**	Class I devices placed on the market in sterile condition	NONVI lux S Non-woven swab, with O-incision, sterile NONVI lux S Non-woven swab, with Y-incision, sterile	DD 1023663-1 NB 0197
elastopor IV IV cannula dressing, non-woven, selfadhesive, sterile **elastoKIDS IV IV cannula dressing, non-woven, selfadhesive, sterile** **Basic UDI-DI: 59079968M04010201H2**	Class I devices placed on the market in sterile condition	elastopor IV IV cannula dressing, non-woven, selfadhesive, sterile elastoKIDS IV IV cannula dressing, non-woven, selfadhesive, sterile	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
elastoDERM F-IV IV cannula dressing, foil, with frame, with U-incision, self-adhesive, sterile **elastoDERM IV IV cannula dressing, foil, selfadhesive, sterile** **elastoDERM Foil dressing, self-adhesive, sterile** **elastoDERM F Foil dressing, with frame, selfadhesive, sterile** **elastoDERM C Foil dressing with a pocket to secure catheter, sterile** **Basic UDI-DI: 59079968M04010202H4**	Class I devices placed on the market in sterile condition	elastoDERM F-IV IV cannula dressing, foil, with frame, with U-incision, self-adhesive, sterile elastoDERM IV IV cannula dressing, foil, selfadhesive, sterile elastoDERM Foil dressing, self-adhesive, sterile elastoDERM F Foil dressing, with frame, selfadhesive, sterile elastoDERM C Foil dressing with a pocket to secure catheter, sterile	DD 1023663-1 NB 0197
MULTIabsorb S **ABD pad, non-woven and cellulose,** **sterile** **Basic UDI-DI: 59079968M040201-SJZ**	Class I devices placed on the market in sterile condition	MULTIabsorb S ABD pad, non-woven and cellulose, sterile	DD 1023663-1 NB 0197
VAGINAL SPECULUM **Basic UDI-DI: 59079968U089006MJ**	Class I devices placed on the market in sterile condition	VAGINAL SPECULUM	DD 1023663-1 NB 0197
URINE BAG **Basic UDI-DI: 59079968A0603038J**	Class I devices placed on the market in sterile condition	URINE BAG	DD 1023663-1 NB 0197
URINE BAG with sample port, sterile **URINE BAG with sample port 2W, sterile** **Basic UDI-DI: 59079968A060303-PBW**	Class I devices placed on the market in sterile condition	URINE BAG with sample port, sterile URINE BAG with sample port 2W, sterile	DD 1023663-1 NB 0197
SAMPLES TAKING URINE BAG for boys, with sponge **SAMPLES TAKING URINE BAG for boys, without sponge** **SAMPLES TAKING URINE BAG for girls, with sponge**	Class I devices placed on the market in sterile condition	SAMPLES TAKING URINE BAG for boys, with sponge SAMPLES TAKING URINE BAG for boys, without sponge	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
SAMPLES TAKING URINE BAG for girls, without sponge **Apteczka ABC Woreczek do pobierania próbek moczu dla dla chłopców z gąbką** **Apteczka ABC Woreczek do pobierania próbek moczu dla dziewczynek z gąbką** **Basic UDI-DI: 59079968A06030301AB**		SAMPLES TAKING URINE BAG for girls, with sponge SAMPLES TAKING URINE BAG for girls, without sponge Apteczka ABC Woreczek do pobierania próbek moczu dla dla chłopców z gąbką Apteczka ABC Woreczek do pobierania próbek moczu dla dziewczynek z gąbką	
ENEMA BAG sterile **Basic UDI-DI: 59079968G020301-SDY**	Class I devices placed on the market in sterile condition	ENEMA BAG sterile	DD 1023663-1 NB 0197
WOODEN TONGUE DEPRESSOR Sterile **Basic UDI-DI: 59079968V9001-SNM**	Class I devices placed on the market in sterile condition	WOODEN TONGUE DEPRESSOR sterile	DD 1023663-1 NB 0197
NELATON CATHETER **NELATON CATHETER transparent** **Basic UDI-DI: 59079968U010105H9**	Class I devices placed on the market in sterile condition	NELATON CATHETER NELATON CATHETER transparent	DD 1023663-1 NB 0197
GUEDEL AIRWAY **Basic UDI-DI: 59079968R010102FG**	Class I devices placed on the market in sterile condition	GUEDEL AIRWAY	DD 1023663-1 NB 0197
ENDOTRACHEAL TUBE HOLDER, vertical fixation **ENDOTRACHEAL TUBE HOLDER, horizontal fixation** **Basic UDI-DI: 59079968R010380-SNX**	Class I devices placed on the market in sterile condition	ENDOTRACHEAL TUBE HOLDER, vertical fixation ENDOTRACHEAL TUBE HOLDER, horizontal fixation	DD 1023663-1 NB 0197
INTUBATION STYLET TRACHEAL TUBE INTRODUCER CURVED **Basic UDI-DI: 59079968R010380-PNR**	Class I devices placed on the market in sterile condition	INTUBATION STYLET TRACHEAL TUBE INTRODUCER CURVED	DD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
dicoSPIKE Withdrawal cannula with bacteria filter **dicoSPIKE Withdrawal cannula with bacteria and particle filter** **dicoSPIKE Chemo Withdrawal cannula with bacteria and particle filter** **Basic UDI-DI: 59079968A0704KC**	Class I devices placed on the market in sterile condition	dicoSPIKE Withdrawal cannula with bacteria filter dicoSPIKE Withdrawal cannula with bacteria and particle filter dicoSPIKE Chemo Withdrawal cannula with bacteria and particle filter	DD 1023663-1 NB 0197
elastoBAND BASIC S Knltted supporting bandage, sterile **Basic UDI-DI: 59079968M030301-SJT**	Class I devices placed on the market in sterile condition	elastoBAND BASIC S Knltted supporting bandage, sterile	HD 1023663-1 NB 0197
elastoBAND FLEX S Elastic bandage, sterile **Basic UDI-DI: 59079968M030402-SKB**	Class I devices placed on the market in sterile condition	elastoBAND FLEX S Elastic bandage, sterile	DD 1023663-1 NB 0197
elastoFILM Incise film, self-adhesive, sterile **elastoFILM M Incise film, self-adhesive, sterile** **Basic UDI-DI: 59079968T020101GT**	Class I devices placed on the market in sterile condition	elastoFILM Incise film, self-adhesive, sterile elastoFILM M Incise film, self-adhesive, sterile	DD 1023663-1 NB 0197
CERVICAL BRUSH standard **CERVICAL BRUSH special** **Basic UDI-DI: 59079968U089002MA**	Class I devices placed on the market in sterile condition	CERVICAL BRUSH standard CERVICAL BRUSH special	DD 1023663-1 NB 0197
omegapack Surgical set B **Basic UDI-DI: 59079968V0599-EP2**	Class IIb excluding Class IIb implantable non-WET	omegapack Surgical set B Orthopedic surgery set B Universal set B C-section set B Cardiac surgery set B Neurosurgical set B	HD 1023663-1 NB 0197
omegapack Surgical set B	Class IIb excluding Class	omegapack Surgical set B	HD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 59079968V0599-KPE	IIb implantable non-WET	Orthopedic surgery set B Universal set B C-section set B Cardiac surgery set B Neurosurgical set B	
omegapack Surgical set **Basic UDI-DI: 59079968V0599-ANS**	Class IIa	omegapack Surgical set Angiography set C-section set Laparoscopy set Gynecological surgery set Cardiac surgery set Neurosurgical set Orthopedic surgery set Otolaryngologic surgery set Urologic surgery set Delivery set Dressing set Universal set	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-WQ6**	Class IIa	deltaset Central venous access kit Neonatal kit Universal kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-IPA**	Class IIa	deltaset Universal kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-CNW**	Class IIa	deltaset Dialysis kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-NPL**	Class IIa	deltaset Universal kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-OPN**	Class IIa	deltaset Universal kit	HD 1023663-1 NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-FP4**	Class IIa	deltaset Urinary bladder catheterization kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-RPU**	Class IIa	deltaset Sewing kit Suture removal kit Dressing change kit Operating field disinfection kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-SPW**	Class IIa	deltaset Anasthesia kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-NIT3**	Class I devices placed on the market in sterile condition	deltaset Universal kit I	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-UITQ**	Class I devices placed on the market in sterile condition	deltaset Universal kit I	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-BIRX**	Class I devices placed on the market in sterile condition	deltaset Dialysis kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-MISY**	Class I devices placed on the market in sterile condition	deltaset Universal kit I	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-DIS5**	Class I devices placed on the market in sterile condition	deltaset Operating field disinfection kit Operating field disinfection kit I	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-ZIU7**	Class I devices placed on the market in sterile condition	deltaset Suture removal kit I	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-PIT9**	Class I devices placed on the market in sterile condition	deltaset Protective kit I Hygiene kit I Neonatal kit I	HD 1023663-1 NB 0197

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
none			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-05-15	ZARYS_CL607_2024-05-15	Initial issue
2024-06-04	ZARYS_CL607_2024-06-04	Update of the device list, minor correction.
2025-02-12	ZARYS_CL607_2025-02-12	Minor corrections of the devices names.
2025-02-14	ZARYS_CL607_2025-02-14	Update of the device list, minor correction.
2025-10-22	ZARYS_CL607_2025-10-22	Update of the device list, minor correction.

Certificate

Quality Management System
EN ISO 13485:2016 + AC:2018 + A11:2021
ISO 13485:2016

Registration No.:	SX 1023663-1
Certificate Holder:	ZARYS International Group Spółka z ograniczoną odpowiedzialnością, spółka komandytowa ul. Pod Borem 18 41-808 Zabrze Poland
Scope:	Design and development, production and distribution of sterile surgical sets, procedure kits, surgical drapes, sets of surgical drapes, surgical gowns and knitted bandages. Production and distribution of sterile and non-sterile disposable medical devices and non-sterile reusable medical devices. Distribution of in-vitro medical devices.

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.:	84984397-20
Effective date:	2025-12-11
Expiry date:	2026-06-08
Issue date:	2025-12-11

Replaces certificate SX 1023663-1 issued 2023-06-06

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

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜVRheinland®
Precisely Right.

Certificate

Quality Management System
EN ISO 13485:2016 + AC:2018 + A11:2021
ISO 13485:2016

Registration No.: SX 1023663-1

Certificate Holder:
ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	ZARYS International Group Spółka z o.o. sp.k. ul. Pod Borem 18 41-808 Zabrze Poland	Design and development, production and distribution of sterile surgical sets, procedure kits, surgical drapes, sets of surgical drapes, surgical gowns and knitted bandages. Production and distribution of sterile and non-sterile disposable medical devices and non-sterile reusable medical devices. Distribution of in-vitro medical devices.
/02	ZARYS International Group Spółka z o.o. sp.k. ul. Guido Henckela Donnersmarcka 1 41-807 Zabrze Poland	Storage, quality control, release and distribution of medical devices.
/03	ZARYS International Group Spółka z o.o. Produkcja sp.k. ul. Pod Borem 18 41-808 Zabrze Poland	Production of sterile: surgical sets, procedure kids, surgical drapes, sets of surgical drapes, surgical gowns and knitted bandages. Production of non-sterile disposable medical devices.
/04	ZARYS International Group Spółka z o.o. sp.k. ul. Ziemska 44 41-803 Zabrze Poland	Administration. Design and development and distribution of medical devices.

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

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

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Certificate No.
NC-3444

CERTIFICATE

Issued for:

ZARYS International Group
spółka z ograniczoną odpowiedzialnością spółka komandytowa

ul. Pod Borem 18
41-808 Zabrze

Management Systems Certification Bureau of Polski Rejestr Statków S.A., al. gen. Józefa Hallera 126, 80-416 Gdańsk, certifies that the Integrated Management System including the Quality Management System and Environmental Management System of the above Organization has been assessed and found to be in accordance with the requirements of:

ISO 9001:2015
ISO 14001:2015

Scope of certification:

PRODUCTION OF: STERILE MEDICAL DEVICES FOR SINGLE USE, NON-STERILE MEDICAL DEVICES FOR SINGLE AND REUSABLE USE

Place of business:

ul. Ziemska 44
41-803 Zabrze, Polska

ul. Guido Henckela Donnersmarcka 1
41-807 Zabrze, Polska

Scope of certification:

PRODUCTION OF: STERILE MEDICAL DEVICES FOR SINGLE USE, NON-STERILE MEDICAL DEVICES FOR SINGLE AND REUSABLE USE; DISTRIBUTION OF: MEDICAL DEVICES, IN-VITRO DIAGNOSTIC DEVICES

The Certificate is valid until: **16.11.2028**

Gdańsk, 17.11.2025

AC 014

Certification Division Director
Przemysław Gałka