

easyFLOW TS

transfusion set

features

- 2-way sharp closure-piercing device of the drip chamber with anti-slip surface that guarantees tight and reliable connection with containers/bags
- air inlet with anti-bacterial filter and a coloured (red) flap
- pliable drip chamber
- dropper: 20 drops = 1 ml +/- 0,1 ml
- special blood filter with large area, pore size 200 µm
- soft, flexible tubing
- universal Luer-Lock fitting at the end of tubing
- precise safe flow regulator with integrated holder for the closure-piercing device and with hook for securing the tubing
- name of the manufacturer placed on the flow regulator
- both tips of the device additionally secured with protective caps
- single-use
- non-pyrogenic, non-toxic
- packaging: 1 pc./paper-foil with a coloured code (red) identifying the device

indication

- device used for the administration of blood and blood products



REF	version	length
TS*	with phthalates	150 cm
TS-BF**	without phthalates	150 cm



bulk packaging:
250 pcs



easyFLOW LINE

extension tube for infusion pump

features

- tubing made of PVC
- device available in a transparent and amber version for photosensitive medicines
- diameter of the tubing - outer: 2,4 mm; inner: 1,24 mm
- New version of the tubing outer : 2,8 mm; inner: 1,8 mm
- Luer-Lock fitting - male and female
- single-use
- non-pyrogenic, non-toxic
- packaging: 1 pc./paper-foil

indication

- device used to extend infusion line



REF	colour of tube	length	intermediate packaging
P450-BF	transparent	45 cm	50 pcs
P1500-BF	transparent	150 cm	50 pcs
PB1500-BF	amber	150 cm	50 pcs
P2000-BF	transparent	200 cm	50 pcs
PB2000-BF	amber	200 cm	50 pcs



bulk packaging:
24 x 50 pcs

New version of the tubing outer

REF	colour of tube	length	intermediate packaging
P450-18-BF	transparent	45 cm	50 pcs
P1800-18-BF	transparent	180 cm	50 pcs



EC Certificate

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 Swiátko
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

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

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EC Certificate

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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:

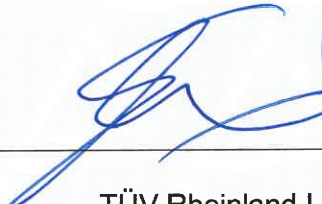
- Elastic bandages
- Adhesive cannula fixation dressings
- Adhesive wound dressings
- Eye pads
- Incise films
- Transparent film dressings
- Foam dressings
- Alginate dressings
- Absorbent wound dressings
- Surgical gowns
- Surgical drapes
- Sets of surgical drapes

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EC Certificate

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



Daniel Świątko
TÜV Rheinland LGA Products GmbH
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EC Certificate

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



Daniel Swiatko
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.

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 February 14, 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/ 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 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.

TÜV Rheinland
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Board of Management

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Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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

 Malgorzata Blazniak
2025.02.14 12:58:44
+01'00'

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 Basic UDI-DI: 59079968M020107DG	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
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 Gauze lap sponges with X-ray chip, pre-washed, sterile	Class IIa	SERVI lux S Gauze lap sponges with X-ray chip, pre-washed, 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: 59079968M02010302-PE86			
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
TUPFER lux Gauze balls without X-ray thread, non-sterile	Class IIa	TUPFER lux Gauze balls without X-ray thread, 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: 59079968M02010501-NTP			
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 Non-woven swabs with X-ray thread, sterile	Class IIa	NONVI lux S Non-woven swabs 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
Basic UDI-DI: 59079968M02020102-ESF			
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 Basic UDI-DI: 59079968R030103-FMV5	Class IIa	NEBULIZER with T F/M adaptor, mouthpiece, corrugated tube and tubing	DD 1023663-1 NB 0197
NEBULIZER mask with tubing	Class IIa	NEBULIZER with mask 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-MMN			
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
Two-way Foley catheter with plastic valve (silicone-coated latex)	Class IIa	TWO-WAY FOLEY CATHETER with plastic 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
Basic UDI-DI: 59079968U010201-LPXD			
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 Basic UDI-DI: 59079968A06010184	Class IIa	SUCTION CANNULA with suction control SUCTION CANNULA without suction control	DD 1023663-1 NB 0197
SUCTION CANNULA with suction control, ball tip	Class IIa	SUCTION CANNULA 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
SUCTION CANNULA without suction control, ball tip Basic UDI-DI: 59079968A060101-BA2		suction control, ball tip SUCTION CANNULA without suction control, ball tip	
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 Basic UDI-DI: 59079968A060304-FCFW	Class IIa	SUCTION TUBE funnel-funnel cut-to-fit	DD 1023663-1 NB 0197
SUCTION TUBE funnel-Kapkon	Class IIa	SUCTION TUBE funnel-Kapkon	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-FKGE			
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 easyFLOW IS SAFE PREMIUM Safety infusion set, phthalate-free	Class IIa	easyFLOW IS SAFE Safety infusion set, phthalate-free easyFLOW IS SAFE PREMIUM Safety infusion set, phthalate-free	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: 59079968A03010103-SG2			
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 Basic UDI-DI: 59079968R0201Q8	Class IIa	BREATHING CIRCUIT FOR CHILDREN BREATHING CIRCUIT FOR ADULTS	DD 1023663-1 NB 0197
CATHETER MOUNT with double swivel elbow connector, smooth-bore	Class IIa	CATHETER MOUNT with double swivel	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: 59079968R020202-SMP		elbow connector, smooth-bore	
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 Basic UDI-DI: 59079968R0202-EGT	Class IIa	CATHETER MOUNT with elbow connector, expandable	DD 1023663-1 NB 0197
TRACHEOSTOMY TUBE cuffed	Class IIa	TRACHEOSTOMY TUBE cuffed	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: 59079968R010502G4			
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) Basic UDI-DI: 59079968A0201020201DQ	Class IIa	dicoNEX Single use syringe, 3-part (luer lock)	DD 1023663-1 NB 0197
dicoNEX Single use amber syringe, 3-part (luer lock)	Class IIa	dicoNEX	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: 59079968A0201020201-AVY		Single use amber syringe, 3-part (luer lock)	
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 Basic UDI-DI: 59079968A02010672	Class IIa	dicoSULIN Insulin syringe	DD 1023663-1 NB 0197
dicoTUBER Tuberculin syringe	Class IIa	dicoTUBER Tuberculin 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: 59079968A02010978			
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: 59079968A01010101026Q	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 NEEDLE FREE VALVE transparent with extension line, triple	Class IIa	NEEDLE FREE VALVE transparent with extension line, single NEEDLE FREE VALVE transparent with extension line, double 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, quadruple Basic UDI-DI: 59079968A070502-LCQ		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 latex, powder-free, sterile	DD 1023663-1 NB 0197
safeCARE synthetic Surgical gloves	Class IIa	safeCARE synthetic Surgical	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
neoprene, powder-free, sterile safeCARE synthetic UG Surgical gloves neoprene, powder-free, sterile Basic UDI-DI: 59079968T010102-NRWL		gloves neoprene, powder-free, sterile safeCARE synthetic UG Surgical gloves neoprene, powder-free, sterile	
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
deltaset Procedure kit O	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
Basic UDI-DI: 59079968V0599-CHRY			
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: 59079968T0305RB	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 Basic UDI-DI: 59079968M040101-FHU	Class I devices placed on the market in sterile condition	elastoDERM PAD Foil dressing, with absorbent pad, self-adhesive, 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
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 Basic UDI-DI: 59079968T020402HC	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 impermeable parts, 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 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 central fenestration, 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 ALPHAtex 3-layer surgical drape with adhesive edge, sterile ALPHAtex 3-layer surgical drape with central fenestration, 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 adhesive fenestration, sterile ALPHAtex Reinforced surgical drape with adhesive fenestration, sterile Basic UDI-DI: 59079968T0201QW		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 central adhesive fenestration, sterile	HD 1023663-1 NB 0197
ALPHAtex Instrument table cover, sterile	Class I devices placed on the	ALPHAtex Instrument table cover, 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: 59079968T030101-INJ	market in sterile condition		
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 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	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 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 ALPHAtex C-section drape, sterile ALPHAtex Delivery drape, sterile ALPHAtex Extremity 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 ALPHAtex Cardiology drape, sterile ALPHAtex Cardiac drape, sterile ALPHAtex C-section drape, sterile ALPHAtex Delivery drape, sterile ALPHAtex Extremity 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 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 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 ALPHAtex Orthopaedic drape, sterile ALPHAtex Shoulder 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) ALPHAtex Extremity drape (from 1 to 100) ALPHAtex Gynaecology	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 Vertical isolation drape, sterile Basic UDI-DI: 59079968T0202QY		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 ALPHAtex Gynaecology set, sterile ALPHAtex Hip set, sterile ALPHAtex Laparoscopy 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 ALPHAtex Dental set, sterile ALPHAtex Dynamic hip screw 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 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 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	
ALPHAtex Abdominal set, sterile ALPHAtex Abdo-Perineal set, sterile ALPHAtex Ablation 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)	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 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 ALPHAtex TUR set, sterile ALPHAtex Universal set, sterile ALPHAtex Uro/gynaecology set, sterile		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) ALPHAtex Ophthalmic set (from 1 to 200) ALPHAtex Otolaryngology set (from 1 to 200)	

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 Varicose vein set, sterile ALPHAtex Vertical isolation set, sterile Basic UDI-DI: 59079968T0202QY		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, self-adhesive, sterile	DD 1023663-1 NB 0197
COMBI STOPPER Basic UDI-DI: 59079968C01018085	Class I devices placed on the market in sterile condition	COMBI STOPPER	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
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
elastoDERM F-IV IV cannula dressing, foil, with frame, with U-incision, self-adhesive, sterile elastoDERM IV IV cannula dressing, foil, selfadhesive, sterile	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,	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 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		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	
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 SAMPLES TAKING URINE BAG for girls, without sponge Apteczka ABC Woreczek do pobierania próbek moczu dla dla chłopców z gąbką	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 SAMPLES TAKING URINE BAG for girls, with sponge SAMPLES TAKING URINE BAG for girls, 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
Apteczka ABC Woreczek do pobierania próbek moczu dla dziewczynek z gąbką Basic UDI-DI: 59079968A06030301AB		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
dicoSPIKE Withdrawal cannula with bacteria filter dicoSPIKE Withdrawal cannula with bacteria and particle filter	Class I devices placed on the market in sterile condition	dicoSPIKE Withdrawal cannula with bacteria filter dicoSPIKE Withdrawal cannula 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
dicoSPIKE Chemo Withdrawal cannula with bacteria and particle filter Basic UDI-DI: 59079968A0704KC		bacteria and particle filter dicoSPIKE Chemo Withdrawal cannula with bacteria and particle filter	
elastoBAND BASIC S Knitted supporting bandage, sterile Basic UDI-DI: 59079968M030301-SJT	Class I devices placed on the market in sterile condition	elastoBAND BASIC S Knitted 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: 59079968U090303L7	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 Basic UDI-DI: 59079968V0599-KPE	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

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
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	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
deltaset Procedure kit Basic UDI-DI: 59079968V0599-FP4	Class IIa	deltaset Urinary bladder catheterization kit	HD 1023663-1 NB 0197
deltaset Procedure kit	Class IIa	deltaset Sewing kit Suture removal 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
Basic UDI-DI: 59079968V0599-RPU		Dressing change kit	
deltaset Procedure kit Basic UDI-DI: 59079968V0599-SPW	Class IIa	deltaset Anesthesia 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.

Certificate

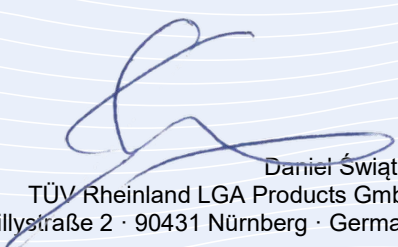
Quality Management System EN ISO 13485:2016

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 diagnostic 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.	84965698-20
Effective date	2023-06-09
Expiry date	2026-06-08
Issue date	2023-06-06
Replaces certificate SX 1023663-1 issued 2021-05-14	

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


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Certificate

Quality Management System EN 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 diagnostic medical devices.
/02	ZARYS International Group Spółka z o.o. sp.k. ul. Guido Henckela Donnersmarcka 1 41-808 Zabrze Poland	Storage, quality control, release and distribution of medical devices.
/03	ZARYS International Group Sp. 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.

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


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Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **0198 100 2241589**

No.	Location	Scope
/01	ZARYS International Group Spółka z ograniczoną odpowiedzialnością, spółka komandytowa ul. Pod Borem 18 41-808 Zabrze Poland	Manufacture of: sterile single-use medical devices, non-sterile single-use and multi-use medical devices; distribution of: medical devices, in vitro diagnostic devices.
/02	ZARYS International Group Spółka z ograniczoną odpowiedzialnością, spółka komandytowa Guido Henckela Donnersmarcka 1 41-807 Zabrze Poland	Manufacture of: sterile single-use medical devices, non-sterile single-use and multi-use medical devices; distribution of: medical devices, in vitro diagnostic devices.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **0198 100 2241589**

/04

ZARYS International Group
Spółka z ograniczoną
odpowiedzialnością
Spółka komandytowa
ul. Ziemska 44
41-803 Zabrze
Poland

Manufacture of: sterile single-use medical
devices, non-sterile single-use and multi-use
medical devices; distribution of: medical
devices, in vitro diagnostic devices.

2024-12-20

Grzegorz Guabka

TÜV Rheinland Polska Sp. z o.o.
ul. Wolności 347, 41-800 Zabrze

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