

# 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 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

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

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Spółka z ograniczoną odpowiedzialnością,  
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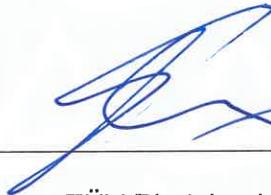
- Sterile breathing circuits
- Sterile catheter mounts
- Non-sterile anaesthetic masks
- Sterile laryngeal masks
- Sterile oxygen masks
- Sterile Venturi masks
- Sterile non-rebreath masks
- Sterile nebulizer masks
- Sterile nasal oxygen cannulas
- Sterile nebulizers
- Sterile oxygen tubing
- Sterile 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



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

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# EC Certificate

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

Registration No.: DD 1023663-1

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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



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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

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Daniel Świątko  
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Tillystraße 2 · 90431 Nürnberg · Germany

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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](mailto: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

TÜV Rheinland  
LGA Products GmbH

Am Grauen Stein  
51105 Köln  
Germany

Headquarter

Tillystraße 2  
90431 Nuremberg

Phone. +49 911 655 5225  
Fax +49 911 655 5226  
service@de.tuv.com  
[www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

Dipl.-Ing.  
Thomas Weigand, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Nuremberg HRB 26013  
VAT No.: DE 811835490

Chairman of the  
Supervisory Board

Dr.-Ing. Michael Fübi

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
<b>GAZA lux S Cutting gauze, sterile</b>  <b>Basic UDI-DI: 59079968M02010101-ERR</b>	Class IIa	GAZA lux S Cutting gauze, sterile	DD 1023663-1 NB 0197
<b>GAZA lux S Cutting gauze, sterile</b>  <b>Basic UDI-DI: 59079968M02010101-SSM</b>	Class IIa	GAZA lux S Cutting gauze, sterile	DD 1023663-1 NB 0197
<b>GAZA lux Cutting gauze, non-sterile</b>  <b>Basic UDI-DI: 59079968M02010101-NSB</b>	Class IIa	GAZA lux Cutting gauze, non-sterile	DD 1023663-1 NB 0197
<b>GAZA lux Dressing gauze, non-sterile</b>	Class IIa	GAZA lux Dressing gauze, non-sterile	DD 1023663-1 NB 0197

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
<b>Basic UDI-DI: 59079968M020107DG</b>			
<b>KOMPRI lux S Gauze swabs without X-ray thread, sterile</b>  <b>Basic UDI-DI: 59079968M02010201-ES4</b>	Class IIa	KOMPRI lux S Gauze swabs without X-ray thread, sterile	DD 1023663-1 NB 0197
<b>KOMPRI lux S Gauze swabs without X-ray thread, sterile</b>  <b>Basic UDI-DI: 59079968M02010201-SSY</b>	Class IIa	KOMPRI lux S Gauze swabs without X-ray thread, sterile	DD 1023663-1 NB 0197
<b>KOMPRI lux S Gauze swabs with X-ray thread, sterile</b>  <b>Basic UDI-DI: 59079968M02010202-ES9</b>	Class IIa	KOMPRI lux S Gauze swabs with X-ray thread, sterile	DD 1023663-1 NB 0197
<b>KOMPRI lux S Gauze swabs with X-ray thread, sterile</b>  <b>Basic UDI-DI: 59079968M02010202-ST5</b>	Class IIa	KOMPRI lux S Gauze swabs with X-ray thread, sterile	DD 1023663-1 NB 0197
<b>KOMPRI lux Gauze swabs without X-ray thread, non-sterile</b>  <b>Basic UDI-DI: 59079968M02010201-NSN</b>	Class IIa	KOMPRI lux Gauze swabs without X-ray thread, non-sterile	DD 1023663-1 NB 0197
<b>KOMPRI lux Gauze swabs with X-ray thread, non-sterile</b>  <b>Basic UDI-DI: 59079968M02010202-NST</b>	Class IIa	KOMPRI lux Gauze swabs with X-ray thread, non-sterile	DD 1023663-1 NB 0197
<b>SERVI lux S Gauze lap sponges with X-ray thread, sterile</b>  <b>Basic UDI-DI: 59079968M02010302-ESL</b>	Class IIa	SERVI lux S Gauze lap sponges with X-ray thread, sterile	DD 1023663-1 NB 0197
<b>SERVI lux S Gauze lap sponges with X-ray thread, sterile</b>  <b>Basic UDI-DI: 59079968M02010302-STG</b>	Class IIa	SERVI lux S Gauze lap sponges with X-ray thread, sterile	DD 1023663-1 NB 0197
<b>SERVI lux S</b>	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
<p>Gauze lap sponges with X-ray chip, pre-washed, sterile</p> <p>Basic UDI-DI: 59079968M02010302-PE86</p>		chip, pre-washed, sterile	
<p>SERVI lux S Gauze lap sponges with X-ray chip, pre-washed, sterile</p> <p>Basic UDI-DI: 59079968M02010302-PS92</p>	Class IIa	SERVI lux S Gauze lap sponges with X-ray chip, pre-washed, sterile	DD 1023663-1 NB 0197
<p>SERVI lux Gauze lap sponges with X-ray thread, non-sterile</p> <p>Basic UDI-DI: 59079968M02010302-NT6</p>	Class IIa	SERVI lux Gauze lap sponges with X-ray thread, non-sterile	DD 1023663-1 NB 0197
<p>SERVI lux Gauze lap sponges with X-ray chip, pre-washed, non-sterile</p> <p>Basic UDI-DI: 59079968M02010302-PN8Q</p>	Class IIa	SERVI lux Gauze lap sponges with X-ray chip, pre-washed, non-sterile	DD 1023663-1 NB 0197
<p>TUPFER lux S Gauze balls without X-ray thread, sterile</p> <p>Basic UDI-DI: 59079968M02010501-ET5</p>	Class IIa	TUPFER lux S Gauze balls without X-ray thread, sterile	DD 1023663-1 NB 0197
<p>TUPFER lux S Gauze balls without X-ray thread, sterile</p> <p>Basic UDI-DI: 59079968M02010501-STZ</p>	Class IIa	TUPFER lux S Gauze balls without X-ray thread, sterile	DD 1023663-1 NB 0197
<p>TUPFER lux S Gauze balls with X-ray thread, sterile</p> <p>Basic UDI-DI: 59079968M02010502-ETA</p>	Class IIa	TUPFER lux S Gauze balls with X-ray thread, sterile	DD 1023663-1 NB 0197
<p>TUPFER lux S Gauze balls with X-ray thread, sterile</p> <p>Basic UDI-DI: 59079968M02010502-SU6</p>	Class IIa	TUPFER lux S Gauze balls with X-ray thread, sterile	DD 1023663-1 NB 0197

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

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
<b>Non-woven swabs with X-ray thread, sterile</b>  <b>Basic UDI-DI: 59079968M02020102-ESF</b>		Non-woven swabs with X-ray thread, sterile	NB 0197
<b>NONVI lux S Non-woven swabs with X-ray thread, sterile</b>  <b>Basic UDI-DI: 59079968M02020102-STB</b>	Class IIa	NONVI lux S Non-woven swabs with X-ray thread, sterile	DD 1023663-1 NB 0197
<b>NONVI lux Non-woven swabs, non-sterile</b>  <b>Basic UDI-DI: 59079968M02020101-NSU</b>	Class IIa	NONVI lux Non-woven swabs, non-sterile	DD 1023663-1 NB 0197
<b>NONVI lux Non-woven swabs with X-ray thread, non-sterile</b>  <b>Basic UDI-DI: 59079968M02020102-NSZ</b>	Class IIa	NONVI lux Non-woven swabs with X-ray thread, non-sterile	DD 1023663-1 NB 0197
<b>paraffiNET Paraffin gauze dressing, sterile</b>  <b>Basic UDI-DI: 59079968M020302DG</b>	Class IIa	paraffiNET Paraffin gauze dressing, sterile	DD 1023663-1 NB 0197
<b>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</b>  <b>Basic UDI-DI: 59079968C0101017F</b>	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
<b>OXYGEN TUBING</b>  <b>Basic UDI-DI: 59079968R03010204LA</b>	Class IIa	OXYGEN TUBING	DD 1023663-1 NB 0197
<b>NEBULIZER with T F/M adaptor, mouthpiece, corrugated tube and tubing</b>	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
<b>Basic UDI-DI: 59079968R030103-FMV5</b>			
<b>NEBULIZER mask with tubing</b>  <b>Basic UDI-DI: 59079968R030103-MMN</b>	Class IIa	NEBULIZER with mask and tubing	DD 1023663-1 NB 0197
<b>OXYGEN MASK with tubing</b>  <b>Basic UDI-DI: 59079968R03010201L4</b>	Class IIa	OXYGEN MASK with tubing	DD 1023663-1 NB 0197
<b>NON-REBREATHER MASK with tubing</b>  <b>Basic UDI-DI: 59079968R03010206LE</b>	Class IIa	NON-REBREATHER MASK with tubing	DD 1023663-1 NB 0197
<b>VENTURI MASK with adjustable diluter and tubing</b>  <b>Basic UDI-DI: 59079968R03010202-AXK</b>	Class IIa	VENTURI MASK with adjustable diluter and tubing	DD 1023663-1 NB 0197
<b>NASAL OXYGEN CANNULA for adults NASAL OXYGEN CANNULA for children NASAL OXYGEN CANNULA for infants</b>  <b>Basic UDI-DI: 59079968R03010203L8</b>	Class IIa	NASAL OXYGEN CANNULA for adults NASAL OXYGEN CANNULA for children NASAL OXYGEN CANNULA for infants	DD 1023663-1 NB 0197
<b>SUCTION CATHETER SUCTION CATHETER with frozen surface, phthalate-free SUCTION CATHETER IDEAL SUCTION CATHETER with vacuum control SUCTION CATHETER with vacuum control IDEAL</b>  <b>Basic UDI-DI: 59079968R0501QP</b>	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
<b>Two-way Foley catheter with rubber valve (silicone-coated latex)</b>  <b>Basic UDI-DI: 59079968U010201-LRXH</b>	Class IIa	TWO-WAY FOLEY CATHETER with rubber valve	DD 1023663-1 NB 0197

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

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
<b>Basic UDI-DI: 59079968A060304-FCFW</b>			
<b>SUCTION TUBE funnel-Kapkon</b>	Class IIa	SUCTION TUBE funnel-Kapkon	DD 1023663-1 NB 0197
<b>Basic UDI-DI: 59079968A060304-FKGE</b>			
<b>easyWAY Three-way stopcock</b>	Class IIa	easyWAY Three-way stopcock	DD 1023663-1 NB 0197
<b>Basic UDI-DI: 59079968A0703KA</b>			
<b>easyWAY L Three-way stopcock with extension</b>	Class IIa	easyWAY L Three-way stopcock with extension	DD 1023663-1 NB 0197
<b>Basic UDI-DI: 59079968A0703-LA4</b>			
<b>easyFLOW LINE Extension tube for infusion pump, phthalate-free</b>	Class IIa	easyFLOW LINE Extension tube for infusion pump, phthalate-free	DD 1023663-1 NB 0197
<b>Basic UDI-DI: 59079968A03020178</b>			
<b>easyFLOW LINE AMBER Extension tube for infusion pump, amber, phthalate-free</b>	Class IIa	easyFLOW LINE AMBER Extension tube for infusion pump, amber, phthalate-free	DD 1023663-1 NB 0197
<b>Basic UDI-DI: 59079968A030201-A8Q</b>			
<b>easyFLOW IS Infusion set easyFLOW IS ECO Infusion set</b>	Class IIa	easyFLOW IS Infusion set easyFLOW IS ECO Infusion set	DD 1023663-1 NB 0197
<b>Basic UDI-DI: 59079968A03010103-PHT6H</b>			
<b>easyFLOW IS Infusion set, phthalate-free easyFLOW IS ECO Infusion set, phthalate-free easyFLOW IS PREMIUM Infusion set, phthalate-free</b>	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
<b>Basic UDI-DI: 59079968A030101037U</b>			
<b>easyFLOW IS SAFE Safety infusion set, phthalate-free</b>	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
<b>easyFLOW IS SAFE PREMIUM Safety infusion set, phthalate-free</b>  <b>Basic UDI-DI:</b> <b>59079968A03010103-SG2</b>		infusion set, phthalate-free easyFLOW IS SAFE PREMIUM Safety infusion set, phthalate-free	
<b>easyFLOW IS REG Infusion set with precision flow rate regulator, phthalate-free</b>  <b>Basic UDI-DI:</b> <b>59079968A03010103-RFY</b>	Class IIa	easyFLOW IS REG Infusion set with precision flow rate regulator, phthalate-free	DD 1023663-1 NB 0197
<b>easyFLOW IS AMBER Infusion set, amber, phthalate-free</b>  <b>Basic UDI-DI:</b> <b>59079968A03010103-AEW</b>	Class IIa	easyFLOW IS AMBER Infusion set, amber, phthalate-free	DD 1023663-1 NB 0197
<b>ENDOTRACHEAL TUBE UNCUFFED</b>  <b>Basic UDI-DI:</b> <b>59079968R010301FQ</b>	Class IIa	ENDOTRACHEAL TUBE UNCUFFED	DD 1023663-1 NB 0197
<b>ENDOTRACHEAL TUBE CUFFED</b>  <b>Basic UDI-DI:</b> <b>59079968R010302FS</b>	Class IIa	ENDOTRACHEAL TUBE CUFFED	DD 1023663-1 NB 0197
<b>REINFORCED ENDOTRACHEAL TUBE CUFFED WITH PRELOADED STYLET</b>  <b>Basic UDI-DI:</b> <b>59079968R010302-RMF</b>	Class IIa	REINFORCED ENDOTRACHEAL TUBE CUFFED WITH PRELOADED STYLET	DD 1023663-1 NB 0197
<b>BREATHING CIRCUIT FOR CHILDREN with bag, expandable, additional arm</b> <b>BREATHING CIRCUIT FOR ADULTS with bag, expandable, additional arm</b>  <b>Basic UDI-DI:</b> <b>59079968R0201-BGG</b>	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
<b>BREATHING CIRCUIT FOR CHILDREN</b> <b>BREATHING CIRCUIT FOR ADULTS</b>	Class IIa	BREATHING CIRCUIT FOR CHILDREN BREATHING CIRCUIT FOR ADULTS	DD 1023663-1 NB 0197

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

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

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
<b>Basic UDI-DI: 59079968A02010672</b>			
<b>dicoTUBER Tuberculin syringe</b>  <b>Basic UDI-DI: 59079968A02010978</b>	Class IIa	dicoTUBER Tuberculin syringe	DD 1023663-1 NB 0197
<b>dispoFINE Injection needle</b>  <b>Basic UDI-DI: 59079968A0101010102CK</b>	Class IIa	dispoFINE Injection needle	DD 1023663-1 NB 0197
<b>dispoGUARD Safety injection needle</b>  <b>Basic UDI-DI: 59079968A0101010101CH</b>	Class IIa	dispoGUARD Safety injection needle	DD 1023663-1 NB 0197
<b>dispoSULIN Insulin pen needle</b>  <b>Basic UDI-DI: 59079968A01010101026Q</b>	Class IIa	dispoSULIN Insulin pen needle	DD 1023663-1 NB 0197
<b>easyFLOW TS Transfusion set</b>  <b>Basic UDI-DI: 59079968A03010102- PHT66</b>	Class IIa	easyFLOW TS Transfusion set	DD 1023663-1 NB 0197
<b>easyFLOW TS Transfusion set, phthalate-free easyFLOW TS PREMIUM Transfusion set, phthalate-free</b>  <b>Basic UDI-DI: 59079968A030101027S</b>	Class IIa	easyFLOW TS Transfusion set, phthalate-free easyFLOW TS PREMIUM Transfusion set, phthalate-free	DD 1023663-1 NB 0197
<b>NEEDLE FREE VALVE blue</b>  <b>Basic UDI-DI: 59079968A0705KE</b>	Class IIa	NEEDLE FREE VALVE blue	DD 1023663-1 NB 0197
<b>NEEDLE FREE VALVE transparent</b>  <b>Basic UDI-DI: 59079968A07050295</b>	Class IIa	NEEDLE FREE VALVE transparent	DD 1023663-1 NB 0197
<b>NEEDLE FREE VALVE transparent with extension line, single NEEDLE FREE VALVE transparent with extension line, double</b>	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
<p><b>NEEDLE FREE VALVE transparent with extension line, triple</b>  <b>NEEDLE FREE VALVE transparent with extension line, quadruple</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968A070502-LCQ</b></p>		<p>with extension line, double  NEEDLE FREE VALVE transparent with extension line, triple  NEEDLE FREE VALVE transparent with extension line, quadruple</p>	
<p><b>safeCARE Surgical gloves, latex, powdered, sterile</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968T01010101-RYM</b></p>	Class IIa	safeCARE Surgical gloves, latex, powdered, sterile	DD 1023663-1 NB 0197
<p><b>safeCARE PF Surgical gloves, latex, powder free, sterile</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968T01010102-RYS</b></p>	Class IIa	safeCARE PF Surgical gloves, latex, powder free, sterile	DD 1023663-1 NB 0197
<p><b>safeCARE basic Surgical gloves latex, powdered, sterile</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968T01010101-RYM</b></p>	Class IIa	safeCARE basic Surgical gloves latex, powdered, sterile	DD 1023663-1 NB 0197
<p><b>safeCARE basic PF Surgical gloves latex, powder-free, sterile</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968T01010102-RYS</b></p>	Class IIa	safeCARE basic PF Surgical gloves latex, powder-free, sterile	DD 1023663-1 NB 0197
<p><b>safeCARE premium Surgical gloves latex, powder-free, sterile</b>  <b>safeCARE UG Surgical gloves latex, powder-free, sterile</b>  <b>safeCARE micro Surgical gloves latex, powder-free, sterile</b>  <b>safeCARE ortho Surgical gloves latex, powder-free, sterile</b>  <b>safeCARE dual Surgical gloves latex, powder-free, sterile</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968T01010102-RYS</b></p>	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

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	
<b>safeCARE synthetic Surgical gloves neoprene, powder-free, sterile</b> <b>safeCARE synthetic UG Surgical gloves neoprene, powder-free, sterile</b>  <b>Basic UDI-DI: 59079968T010102-NRWL</b>	Class IIa	safeCARE synthetic Surgical gloves neoprene, powder-free, sterile safeCARE synthetic UG Surgical gloves neoprene, powder-free, sterile	DD 1023663-1 NB 0197
<b>safeCARE fusion Surgical gloves polyisoprene, powder-free, sterile</b>  <b>Basic UDI-DI: 59079968T010102-PRWS</b>	Class IIa	safeCARE fusion Surgical gloves polyisoprene, powder-free, sterile	DD 1023663-1 NB 0197
<b>safeCARE virtuo Surgical gloves flexylon, powder-free, sterile</b> <b>safeCARE virtuo UG Surgical gloves flexylon, powder-free, sterile</b> <b>safeCARE pro protect Surgical gloves flexylon, powder-free, sterile</b>  <b>Basic UDI-DI: 59079968T010102-FRVU</b>	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
<b>safeLANCE Pressure-activated safety lancet</b>  <b>Basic UDI-DI: 59079968V0104RM</b>	Class IIa	safeLANCE Pressure-activated safety lancet	DD 1023663-1 NB 0197
<b>deltaset Procedure kit O</b>  <b>Basic UDI-DI: 59079968V0599-SETA</b>	Class IIa	deltaset Urinary bladder catheterization kit	DD 1023663-1 NB 0197
<b>deltaset Procedure kit O</b>  <b>Basic UDI-DI: 59079968V0599-SHTG</b>	Class IIa	deltaset Urinary bladder catheterization kit	DD 1023663-1 NB 0197
<b>deltaset Procedure kit O</b>  <b>Basic UDI-DI: 59079968V0599-CERS</b>	Class IIa	deltaset Dialysis kit	DD 1023663-1 NB 0197

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
<b>deltaset Procedure kit O</b>  <b>Basic UDI-DI: 59079968V0599-CHRY</b>	Class IIa	deltaset Dialysis kit	DD 1023663-1 NB 0197
<b>deltaset Procedure kit O</b>  <b>Basic UDI-DI: 59079968V0599-WETN</b>	Class IIa	deltaset Dressing change kit	DD 1023663-1 NB 0197
<b>deltaset Procedure kit O</b>  <b>Basic UDI-DI: 59079968V0599-WHTU</b>	Class IIa	deltaset Dressing change kit	DD 1023663-1 NB 0197
<b>deltaset Procedure kit O</b>  <b>Basic UDI-DI: 59079968V0599-RET7</b>	Class IIa	deltaset Suture application kit deltaset Suture removal kit	DD 1023663-1 NB 0197
<b>deltaset Procedure kit O</b>  <b>Basic UDI-DI: 59079968V0599-RHTD</b>	Class IIa	deltaset Suture application kit deltaset Suture removal kit	DD 1023663-1 NB 0197
<b>deltaset Procedure kit O</b>  <b>Basic UDI-DI: 59079968V0599-IESC</b>	Class IIa	deltaset Anesthesia kit deltaset Puncture kit	DD 1023663-1 NB 0197
<b>deltaset Procedure kit O</b>  <b>Basic UDI-DI: 59079968V0599-IHSJ</b>	Class IIa	deltaset Anesthesia kit deltaset Puncture kit	DD 1023663-1 NB 0197
<b>elastopor STERIL Non-woven dressing with absorbent pad, self-adhesive, sterile</b> <b>elastoKIDS STERIL Non-woven dressing with absorbent pad, self-adhesive, sterile</b>  <b>Basic UDI-DI: 59079968M040101-WJW</b>	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
<b>elastoDERM PAD Foil dressing, with absorbent pad, self-adhesive, sterile</b>	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
<p>central fenestration, sterile  <b>ALPHAtex 3-layer surgical drape with central adhesive fenestration, sterile</b>  <b>ALPHAtex Reinforced surgical drape with adhesive fenestration, sterile</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968T0201QW</b></p>		<p>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</p>	
<p><b>ALPHAtex Surgical drape</b>  <b>ALPHAtex 2-layer surgical drape, with cellulose layer</b>  <b>ALPHAtex 2-layer surgical drape</b>  <b>ALPHAtex 2-layer surgical drape with adhesive edge</b>  <b>ALPHAtex 2-layer surgical drape with central fenestration</b>  <b>ALPHAtex 2-layer surgical drape with central adhesive fenestration</b>  <b>ALPHAtex 3-layer surgical drape</b>  <b>ALPHAtex 3-layer surgical drape with adhesive edge</b>  <b>ALPHAtex 3-layer surgical drape with central fenestration</b>  <b>ALPHAtex 3-layer surgical drape with central adhesive fenestration</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968T0201QW</b></p>	<p>Class I devices placed on the market in sterile condition</p>	<p>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 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</p>	<p>HD 1023663-1  NB 0197</p>

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	
<b>ALPHAtex Instrument table cover, sterile</b>  <b>Basic UDI-DI: 59079968T030101-INJ</b>	Class I devices placed on the market in sterile condition	ALPHAtex Instrument table cover, sterile	DD 1023663-1 NB 0197
<b>ALPHAtex Reinforced Mayo stand cover, sterile</b> <b>ALPHAtex Reinforced Mayo stand cover, red, sterile</b>  <b>Basic UDI-DI: 59079968T030101-MNS</b>	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
<b>ALPHAtex Armboard cover, sterile</b> <b>ALPHAtex Surgical pocket for syringes, sterile</b>  <b>Basic UDI-DI: 59079968T030101-NNU</b>	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
<b>ALPHAtex Camera cables cover, sterile</b> <b>ALPHAtex Circular banded cover for medical devices, sterile</b> <b>ALPHAtex Square banded cover for medical devices, sterile</b> <b>ALPHAtex C-arm cover set, sterile</b> <b>ALPHAtex Lamp handle cover, sterile</b> <b>ALPHAtex Ultrasound cover kits, sterile</b>  <b>Basic UDI-DI: 59079968T030101-FNC</b>	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
<b>ALPHAtex Absorbent drape, sterile</b> <b>ALPHAtex Absorbent drape for newborn, sterile</b>  <b>Basic UDI-DI: 59079968T020199-SRU</b>	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
<b>ALPHAtex Absorbent drape, sterile</b>	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
<p>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</p> <p>Basic UDI-DI:  59079968T0202QY</p>		<p>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</p>	
<p>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</p>	<p>Class I devices placed on the market in sterile condition</p>	<p>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)</p>	<p>HD 1023663-1  NB 0197</p>

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
<p>ALPHAtex Orthopaedic drape, sterile  ALPHAtex Shoulder drape, sterile  ALPHAtex Vertical isolation drape, sterile</p> <p>Basic UDI-DI:  59079968T0202QY</p>		<p>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)</p>	
<p>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</p>	<p>Class I devices placed on the market in sterile condition</p>	<p>ALPHAtex Abdominal set, sterile  ALPHAtex Abdo-Perineal set, sterile  ALPHAtex Ablation set, sterile  ALPHAtex Angiography set, sterile  ALPHAtex Arthroscopy set, sterile  ALPHAtex Cardiology set, sterile  ALPHAtex Cardiac set, sterile  ALPHAtex Craniotomy set, sterile  ALPHAtex Cardiac set, sterile  ALPHAtex Craniotomy set, sterile  ALPHAtex C-section set, sterile  ALPHAtex Cystoscopy set, sterile  ALPHAtex Delivery set, sterile</p>	<p>DD 1023663-1  NB 0197</p>

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
<p>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</p> <p>Basic UDI-DI:  59079968T0202QY</p>		<p>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</p>	

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
<p>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</p>	<p>Class I devices placed on the market in sterile condition</p>	<p>"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 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)</p>	<p>HD 1023663-1  NB 0197</p>

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
<p>ALPHAtex TUR set, sterile  ALPHAtex Universal set, sterile  ALPHAtex Uro/gynaecology set, sterile  ALPHAtex Varicose vein set, sterile  ALPHAtex Vertical isolation set, sterile</p> <p>Basic UDI-DI:  59079968T0202QY</p>		<p>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)"</p>	
<p>elastoLUMENAL S Eye pad, superabsorbent, multi-layer, sterile</p> <p>Basic UDI-DI:  59079968M040301-SKC</p>	<p>Class I devices placed on the market in sterile condition</p>	<p>elastoLUMENAL S Eye pad, superabsorbent, multi-layer, sterile</p>	<p>DD 1023663-1  NB 0197</p>
<p>elastopor EYE Eye dressing, non-woven, with absorbent pad, self-adhesive, sterile  elastoKIDS EYE Eye dressing, non-woven, with absorbent pad, self-adhesive, sterile</p> <p>Basic UDI-DI:  59079968M0403NX</p>	<p>Class I devices placed on the market in sterile condition</p>	<p>lastopor EYE Eye dressing, non-woven, with absorbent pad, self-adhesive, sterile  elastoKIDS EYE Eye dressing, non-woven, with absorbent pad,</p>	<p>DD 1023663-1  NB 0197</p>

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	
<b>COMBI STOPPER</b>  <b>Basic UDI-DI:</b> <b>59079968C01018085</b>	Class I devices placed on the market in sterile condition	COMBI STOPPER	DD 1023663-1 NB 0197
<b>LUER LOCK STOPPER</b>  <b>Basic UDI-DI:</b> <b>59079968C01018085</b>	Class I devices placed on the market in sterile condition	LUER LOCK STOPPER	DD 1023663-1 NB 0197
<b>elastopor STERIL D Non-woven dressing with absorbent pad, with incision and O-hole, self-adhesive, sterile</b> <b>elastoKIDS STERIL D Non-woven dressing, with absorbent pad, with incision and X-hole, self-adhesive, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M04010201-DTG</b>	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 elastoKIDS STERIL D Non-woven dressing, with absorbent pad, with incision and X-hole, self-adhesive, sterile	DD 1023663-1 NB 0197
<b>NONVI lux S Non-woven swab, with O-incision, sterile</b> <b>NONVI lux S Non-woven swab, with Y-incision, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M04010201-NU4</b>	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
<b>elastopor IV IV cannula dressing, non-woven, selfadhesive, sterile</b> <b>elastoKIDS IV IV cannula dressing, non-woven, selfadhesive, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M04010201H2</b>	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
<p><b>elastoDERM F-IV IV cannula dressing, foil, with frame, with U-incision, self-adhesive, sterile</b>  <b>elastoDERM IV IV cannula dressing, foil, selfadhesive, sterile</b>  <b>elastoDERM Foil dressing, self-adhesive, sterile</b>  <b>elastoDERM F Foil dressing, with frame, selfadhesive, sterile</b>  <b>elastoDERM C Foil dressing with a pocket to secure catheter, sterile</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968M04010202H4</b></p>	<p>Class I devices placed on the market in sterile condition</p>	<p>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</p>	<p>DD 1023663-1  NB 0197</p>
<p><b>MULTIabsorb S ABD pad, non-woven and cellulose, sterile</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968M040201-SJZ</b></p>	<p>Class I devices placed on the market in sterile condition</p>	<p>MULTIabsorb S ABD pad, non-woven and cellulose, sterile</p>	<p>DD 1023663-1  NB 0197</p>
<p><b>VAGINAL SPECULUM</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968U089006MJ</b></p>	<p>Class I devices placed on the market in sterile condition</p>	<p>VAGINAL SPECULUM</p>	<p>DD 1023663-1  NB 0197</p>
<p><b>URINE BAG</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968A0603038J</b></p>	<p>Class I devices placed on the market in sterile condition</p>	<p>URINE BAG</p>	<p>DD 1023663-1  NB 0197</p>
<p><b>URINE BAG with sample port, sterile</b>  <b>URINE BAG with sample port 2W, sterile</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968A060303-PBW</b></p>	<p>Class I devices placed on the market in sterile condition</p>	<p>URINE BAG with sample port, sterile  URINE BAG with sample port 2W, sterile</p>	<p>DD 1023663-1  NB 0197</p>
<p><b>SAMPLES TAKING URINE BAG for boys, with sponge</b>  <b>SAMPLES TAKING URINE BAG for boys, without sponge</b>  <b>SAMPLES TAKING URINE BAG for girls, with sponge</b></p>	<p>Class I devices placed on the market in sterile condition</p>	<p>SAMPLES TAKING URINE BAG for boys, with sponge  SAMPLES TAKING URINE BAG for boys, without sponge</p>	<p>DD 1023663-1  NB 0197</p>

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
<p><b>SAMPLES TAKING URINE BAG for girls, without sponge</b>  <b>Apteczka ABC Woreczek do pobierania próbek moczu dla dla chłopców z gąbką</b>  <b>Apteczka ABC Woreczek do pobierania próbek moczu dla dziewczynek z gąbką</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968A06030301AB</b></p>		<p>SAMPLES TAKING URINE BAG for girls, with sponge</p> <p>SAMPLES TAKING URINE BAG for girls, without sponge</p> <p>Apteczka ABC Woreczek do pobierania próbek moczu dla dla chłopców z gąbką</p> <p>Apteczka ABC Woreczek do pobierania próbek moczu dla dziewczynek z gąbką</p>	
<p><b>ENEMA BAG sterile</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968G020301-SDY</b></p>	<p>Class I devices placed on the market in sterile condition</p>	<p>ENEMA BAG sterile</p>	<p>DD 1023663-1  NB 0197</p>
<p><b>WOODEN TONGUE DEPRESSOR</b>  <b>Sterile</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968V9001-SNM</b></p>	<p>Class I devices placed on the market in sterile condition</p>	<p>WOODEN TONGUE DEPRESSOR sterile</p>	<p>DD 1023663-1  NB 0197</p>
<p><b>NELATON CATHETER</b>  <b>NELATON CATHETER transparent</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968U010105H9</b></p>	<p>Class I devices placed on the market in sterile condition</p>	<p>NELATON CATHETER  NELATON CATHETER transparent</p>	<p>DD 1023663-1  NB 0197</p>
<p><b>GUEDEL AIRWAY</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968R010102FG</b></p>	<p>Class I devices placed on the market in sterile condition</p>	<p>GUEDEL AIRWAY</p>	<p>DD 1023663-1  NB 0197</p>
<p><b>ENDOTRACHEAL TUBE HOLDER, vertical fixation</b>  <b>ENDOTRACHEAL TUBE HOLDER, horizontal fixation</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968R010380-SNX</b></p>	<p>Class I devices placed on the market in sterile condition</p>	<p>ENDOTRACHEAL TUBE HOLDER, vertical fixation</p> <p>ENDOTRACHEAL TUBE HOLDER, horizontal fixation</p>	<p>DD 1023663-1  NB 0197</p>
<p><b>INTUBATION STYLET TRACHEAL TUBE INTRODUCER CURVED</b></p> <p><b>Basic UDI-DI:</b>  <b>59079968R010380-PNR</b></p>	<p>Class I devices placed on the market in sterile condition</p>	<p>INTUBATION STYLET TRACHEAL TUBE INTRODUCER CURVED</p>	<p>DD 1023663-1  NB 0197</p>

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
<p>dicoSPIKE Withdrawal cannula with bacteria filter  dicoSPIKE Withdrawal cannula with bacteria and particle filter  dicoSPIKE Chemo Withdrawal cannula with bacteria and particle filter</p> <p>Basic UDI-DI:  59079968A0704KC</p>	<p>Class I devices placed on the market in sterile condition</p>	<p>dicoSPIKE Withdrawal cannula with bacteria filter  dicoSPIKE Withdrawal cannula with bacteria and particle filter  dicoSPIKE Chemo Withdrawal cannula with bacteria and particle filter</p>	<p>DD 1023663-1  NB 0197</p>
<p>elastoBAND BASIC S Knitted supporting bandage, sterile</p> <p>Basic UDI-DI:  59079968M030301-SJT</p>	<p>Class I devices placed on the market in sterile condition</p>	<p>elastoBAND BASIC S Knitted supporting bandage, sterile</p>	<p>HD 1023663-1  NB 0197</p>
<p>elastoBAND FLEX S Elastic bandage, sterile</p> <p>Basic UDI-DI:  59079968M030402-SKB</p>	<p>Class I devices placed on the market in sterile condition</p>	<p>elastoBAND FLEX S Elastic bandage, sterile</p>	<p>DD 1023663-1  NB 0197</p>
<p>elastoFILM Incise film, self-adhesive, sterile  elastoFILM M Incise film, self-adhesive, sterile</p> <p>Basic UDI-DI:  59079968T020101GT</p>	<p>Class I devices placed on the market in sterile condition</p>	<p>elastoFILM Incise film, self-adhesive, sterile  elastoFILM M Incise film, self-adhesive, sterile</p>	<p>DD 1023663-1  NB 0197</p>
<p>CERVICAL BRUSH standard  CERVICAL BRUSH special</p> <p>Basic UDI-DI:  59079968U089002MA</p>	<p>Class I devices placed on the market in sterile condition</p>	<p>CERVICAL BRUSH standard  CERVICAL BRUSH special</p>	<p>DD 1023663-1  NB 0197</p>
<p>omegapack Surgical set B</p> <p>Basic UDI-DI:  59079968V0599-EP2</p>	<p>Class IIb excluding Class IIb implantable non-WET</p>	<p>omegapack Surgical set B  Orthopedic surgery set B  Universal set B  C-section set B  Cardiac surgery set B  Neurosurgical set B</p>	<p>HD 1023663-1  NB 0197</p>
<p>omegapack Surgical set B</p>	<p>Class IIb excluding Class</p>	<p>omegapack Surgical set B</p>	<p>HD 1023663-1  NB 0197</p>

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
<b>Basic UDI-DI: 59079968V0599-KPE</b>	IIb implantable non-WET	Orthopedic surgery set B Universal set B C-section set B Cardiac surgery set B Neurosurgical set B	
<b>omegapack Surgical set</b>  <b>Basic UDI-DI: 59079968V0599-ANS</b>	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
<b>deltaset Procedure kit</b>  <b>Basic UDI-DI: 59079968V0599-WQ6</b>	Class IIa	deltaset Central venous access kit Neonatal kit Universal kit	HD 1023663-1 NB 0197
<b>deltaset Procedure kit</b>  <b>Basic UDI-DI: 59079968V0599-IPA</b>	Class IIa	deltaset Universal kit	HD 1023663-1 NB 0197
<b>deltaset Procedure kit</b>  <b>Basic UDI-DI: 59079968V0599-CNW</b>	Class IIa	deltaset Dialysis kit	HD 1023663-1 NB 0197
<b>deltaset Procedure kit</b>  <b>Basic UDI-DI: 59079968V0599-NPL</b>	Class IIa	deltaset Universal kit	HD 1023663-1 NB 0197
<b>deltaset Procedure kit</b>  <b>Basic UDI-DI: 59079968V0599-OPN</b>	Class IIa	deltaset Universal kit	HD 1023663-1 NB 0197

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