

**Verslo srities produktų**  
Sertifikavimo departamentas

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Data Gegužės 15, 2024

*ZARYS International Group spółka z ograniczoną odpowiedzialnością*  
*Komandytowa*  
*Ul. Pod Borem 18,*  
*41-808 Zabrze,*  
*Lenkija*

**Notifikuotos įstaigos patvirtinimo laiškas**

Nuoroda: ZARYS\_PLA0\_HZ\_2024-05-10/84965323

Suinteresuotoms šalims,

**Oficialios paraiškos, rašytinio susitarimo ir tinkamos priežiūros statuso patvirtinimas pagal Reglamentą ES 2023/607, iš dalies keičiantį reglamentus (ES) 2017/745 ir (ES) 2017/746 dėl pereinamojo laikotarpio nuostatų tam tikriems medicinos prietaisams ir Vitro diagnostikos medicinos prietaisams.**

Šiuo laišku patvirtinama, kad TÜV Rheinland LGA Products GmbH, Notifikuotoji įstaiga (NB), paskirta pagal Reglamentą (ES) 2017/745 (MDR) ir pažymėta NANDO numeriu 0197, gavo oficialią paraišką pagal 4.3 skirsnio pirmą pastraipą. ir pasirašė rašytinį susitarimą pagal MDR VII priedo 4.3 skirsnio antrąją pastraipą su šiuo gamintoju:

ZARYS International Group spółka z ograniczoną odpowiedzialnością  
Komandytowa  
Ul. Pod Borem 18,  
41-808 Zabrze,  
Lenkija  
SRN Number: PL-MF-00000410

Įrenginiai, kuriems taikoma oficiali paraiška ir pirmiau minėtas rašytinis susitarimas, nurodyti toliau pateiktose lentelėse. 1 lentelėje nurodyti prietaisai, dėl kurių buvo gauta MDR paraiška, sudaryta rašytinė sutartis ir kurių NB taip pat yra atsakinga už tinkamą priežiūrą pagal taikomą direktyvą. 2 lentelėje nurodyti prietaisai, dėl kurių buvo gauta MDR paraiška ir sudaryta rašytinė sutartis, tačiau NB dar neprisiėmė atsakomybės už tinkamą atitinkamų prietaisų priežiūrą pagal taikomą direktyvą.

Prietaisams, kuriems išduoti sertifikatai pagal Direktyvą 90/385/EEB (AIMDD) arba Direktyvą 93/42/EEB (MDD), kurios galiojimas pasibaigė po 2021 m. gegužės 26 d., bet iki 2023 m. kovo 20 d. ir nebuvo atšauktas, šis raštas taip pat patvirtina, kad gamintojas arba pasirašė rašytinį susitarimą pagal MDR iki MDD datos /AIMDD sertifikato galiojimo arba pateikė įrodymus, kad valstybės narės kompetentinga institucija pagal MDR 59 straipsnio 1 dalį arba MDR 97 straipsnio 1 dalį suteikė taikytinos atitikties vertinimo procedūros leidžiančią nukrypti nuostatą arba išimtį, iki 2023 m. kovo 20 d. atitinkamiems prietaisams.

Pereinamieji terminai, taikomi prietaisams, kuriems taikomas šis raštas, su sąlyga, kad gamintojas ir toliau laikysis kitų sąlygų, nurodytų MDR 120.3c straipsnyje (su pakeitimais, padarytais (ES) 2023/607), nurodyti toliau:

- 2026 m. gegužės 26 d. III klasės individualiems implantuojamiems prietaisams
- 2027 m. gruodžio 31 d. III klasės prietaisams ir IIb klasės implantuojamiems įrenginiams, išskyrus nusistovėjusias technologijas (WET – siūlai, kabės, dantų plombos, dantų breketai, dantų vainikėliai, varžtai, pleištai, plokštelės, laidai, kaiščiai, spaustukai ir jungtys)
- 2028 m. gruodžio 31 d. kitiems IIb klasės, IIa klasės, I klasės prietaisams, kurie pateikiami į rinką sterilūs arba turi matavimo funkciją
- 2028 m. gruodžio 31 d. prietaisams, kuriems pagal MDD nereikia paskelbtosios įstaigos, bet pagal MDR (pvz., I klasės prietaisams, kurie atitinka daugkartinio naudojimo chirurginių instrumentų reikalavimus)

Notifikuotos įstaigos vardu  
(parašas)

Malgorzata Blazniak  
2024.05.15  
Audito peržiūra  
Sertifikavimo įstaiga

1 lentelė. Prietaisai, kuriems taikomas šis raštas ir už kuriuos NB taip pat atsakinga už atitinkamą atitinkamų prietaisų priežiūrą pagal taikomą direktyvą:

Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)	MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)	Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas	MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB identifikavimas
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

<b>GAZA lux Dressing gauze, nonsterile</b>  <b>Basic UDI-DI: 59079968M020107DG</b>	Class IIa	GAZA lux Dressing gauze, non-sterile	DD 1023663-1 NB 0197
<b>KOMPRI lux S</b>	Class IIa	KOMPRI lux S	DD 1023663-1 NB 0197

<b>Prietaiso pavadinimas arba bazinis UDI- DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
<b>Gauze swabs without Xray thread, sterile</b>  <b>Basic UDI-DI: 59079968M02010201-ES4</b>		Gauze swabs without X-ray thread, sterile	
<b>KOMPRI lux S Gauze swabs without Xray 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 Xray 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, nonsterile	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 Gauze lap sponges with X-ray chip, pre-washed, sterile</b>	Class IIa	SERVI lux S Gauze lap sponges with X-ray chip, pre-washed, sterile	DD 1023663-1 NB 0197

<b>Prietaiso pavadinimas arba bazinis UDI- DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
<b>Basic UDI-DI: 59079968M02010302PE86</b>			
<b>SERVI lux S Gauze lap sponges with X-ray chip, pre-washed, sterile</b>  <b>Basic UDI-DI: 59079968M02010302PS92</b>	Class IIa	SERVI lux S Gauze lap sponges with X-ray chip, pre-washed, sterile	DD 1023663-1 NB 0197
<b>SERVI lux Gauze lap sponges with X-ray thread, non-sterile</b>  <b>Basic UDI-DI: 59079968M02010302-NT6</b>	Class IIa	SERVI lux Gauze lap sponges with X-ray thread, non- sterile	DD 1023663-1 NB 0197
<b>SERVI lux Gauze lap sponges with X-ray chip, pre-washed, non-sterile</b>  <b>Basic UDI-DI: 59079968M02010302PN8Q</b>	Class IIa	SERVI lux Gauze lap sponges with X-ray chip, pre- washed, non- sterile	DD 1023663-1 NB 0197

<b>TUPFER lux S</b> <b>Gauze balls without X-ray</b> <b>thread, sterile</b>	Class IIa	TUPFER lux S Gauze balls without X-ray thread, sterile	DD 1023663-1 NB 0197
<b>Basic UDI-DI:</b> <b>59079968M02010501-ET5</b>			
<b>TUPFER lux S</b> <b>Gauze balls without X-ray</b> <b>thread, sterile</b>	Class IIa	TUPFER lux S Gauze balls without X-ray thread, sterile	DD 1023663-1 NB 0197
<b>Basic UDI-DI:</b> <b>59079968M02010501-STZ</b>			
<b>TUPFER lux S</b> <b>Gauze balls with X-ray</b> <b>thread, sterile</b>	Class IIa	TUPFER lux S Gauze balls with Xray thread, sterile	DD 1023663-1 NB 0197
<b>Basic UDI-DI:</b> <b>59079968M02010502-ETA</b>			
<b>TUPFER lux S</b> <b>Gauze balls with X-ray</b> <b>thread, sterile</b>	Class IIa	TUPFER lux S Gauze balls with Xray thread, sterile	DD 1023663-1 NB 0197
<b>Basic UDI-DI:</b> <b>59079968M02010502-SU6</b>			
<b>TUPFER lux</b> <b>Gauze balls without X-ray</b> <b>thread, non-sterile</b>	Class IIa	TUPFER lux Gauze balls without X-ray thread, non-sterile	DD 1023663-1 NB 0197

<b>Prietaiso pavadinimas</b> <b>arba bazinis UDI-</b> <b>DI (pagal MDR</b> <b>paraišką)</b>	<b>MDR prietaiso</b> <b>klasifikacija</b> <b>(kaip pasiūlė</b> <b>gamintojas ir</b> <b>patikrinta prieš</b> <b>paraišką)</b>	<b>Jei MDR</b> <b>prietaisas yra</b> <b>pakaitalas,</b> <b>atitinkamo</b> <b>MDD/AIMDD</b> <b>prietaiso</b> <b>identifikavimas</b>	<b>MDD / AIMDD</b> <b>sertifikato</b> <b>nuoroda</b> <b>prietaisams</b> <b>pagal MDR</b> <b>paraišką ir NB</b> <b>Identifikavimas</b>
<b>Basic UDI-DI:</b> <b>59079968M02010501-NTP</b>			
<b>TUPFER lux</b> <b>Gauze balls with X-ray</b> <b>thread, non-sterile</b>	Class IIa	TUPFER lux Gauze balls with Xray thread, nonsterile	DD 1023663-1 NB 0197
<b>Basic UDI-DI:</b> <b>59079968M02010502-NTU</b>			
<b>SETON lux S</b> <b>Gauze rolls without X-ray</b> <b>thread, sterile</b>	Class IIa	SETON lux S Gauze rolls without X-ray thread, sterile	DD 1023663-1 NB 0197
<b>Basic UDI-DI:</b> <b>59079968M02010701-SUP</b>			
<b>SETON lux S</b> <b>Gauze rolls with X-ray</b> <b>thread, sterile</b>	Class IIa	SETON lux S Gauze rolls with Xray thread, sterile	DD 1023663-1 NB 0197
<b>Basic UDI-DI:</b>			

<b>59079968M02010702-ETY</b>			
<b>SETON lux S</b> <b>Gauze rolls with X-ray</b> <b>thread, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M02010702-SUU</b>	Class IIa	SETON lux S Gauze rolls with Xray thread, sterile	DD 1023663-1 NB 0197
<b>SETON lux</b> <b>Gauze rolls without X-ray</b> <b>thread, non-sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M02010701-NUD</b>	Class IIa	SETON lux Gauze rolls without X-ray thread, nonsterile	DD 1023663-1 NB 0197
<b>SETON lux</b> <b>Gauze rolls with X-ray</b> <b>thread, non-sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M02010702-NUJ</b>	Class IIa	SETON lux Gauze rolls with Xray thread, nonsterile	DD 1023663-1 NB 0197
<b>NONVI lux S</b> <b>Non-woven swab, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M02020101-ESA</b>	Class IIa	NONVI lux S Non- woven swabs, sterile	DD 1023663-1 NB 0197
<b>NONVI lux S</b> <b>Non-woven swab, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M02020101-ST6</b>	Class IIa	NONVI lux S Non- woven swabs, sterile	DD 1023663-1 NB 0197
<b>NONVI lux S</b> <b>Non-woven swabs with</b> <b>Xray thread, sterile</b>	Class IIa	NONVI lux S Non- woven swabs with X-ray thread, sterile	DD 1023663-1 NB 0197

<b>Prietaiso pavadinimas</b> <b>arba bazinis UDI-</b> <b>DI (pagal MDR</b> <b>paraišką)</b>	<b>MDR prietaiso</b> <b>klasifikacija</b> <b>(kaip pasiūlė</b> <b>gamintojas ir</b> <b>patikrinta prieš</b> <b>paraišką)</b>	<b>Jei MDR</b> <b>prietaisas yra</b> <b>pakaitalas,</b> <b>atitinkamo</b> <b>MDD/AIMDD</b> <b>prietaiso</b> <b>identifikavimas</b>	<b>MDD / AIMDD</b> <b>sertifikato</b> <b>nuoroda</b> <b>prietaisams</b> <b>pagal MDR</b> <b>paraišką ir NB</b> <b>Identifikavimas</b>
<b>Basic UDI-DI:</b> <b>59079968M02020102-ESF</b>			
<b>NONVI lux S</b> <b>Non-woven swabs with</b> <b>Xray thread, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M02020102-STB</b>	Class IIa	NONVI lux S Non- woven swabs with X-ray thread, sterile	DD 1023663-1 NB 0197

<b>NONVI lux</b> <b>Non-woven swabs, non-sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M02020101-NSU</b>	Class IIa	<b>NONVI lux</b> <b>Non-woven swabs, non-sterile</b>	DD 1023663-1 NB 0197
<b>NONVI lux</b> <b>Non-woven swabs with Xray thread, non-sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M02020102-NSZ</b>	Class IIa	<b>NONVI lux</b> <b>Non-woven swabs with X-ray thread, non-sterile</b>	DD 1023663-1 NB 0197
<b>paraffiNET</b> <b>Paraffin gauze dressing, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M020302DG</b>	Class IIa	<b>paraffiNET</b> Paraffin gauze dressing, sterile	DD 1023663-1 NB 0197
<b>SANVIflon I.V. cannula</b> <b>SANVIflon S I.V. cannula without injection port</b> <b>SANVIflon premium I.V. cannula</b> <b>SANVIflon safe Safety I.V. cannula</b>  <b>Basic UDI-DI:</b> <b>59079968C0101017F</b>	Class IIa	<b>SANVIflon I.V. cannula</b> <b>SANVIflon S I.V. cannula without injection port</b> <b>SANVIflon premium I.V. cannula</b> <b>SANVIflon safe</b> <b>Safety I.V. cannula</b>	DD 1023663-1 NB 0197
<b>OXYGEN TUBING</b>  <b>Basic UDI-DI:</b> <b>59079968R03010204LA</b>	Class IIa	<b>OXYGEN TUBING</b>	DD 1023663-1 NB 0197
<b>NEBULIZER with T F/M adaptor, mouthpiece, corrugated tube and tubing</b>  <b>Basic UDI-DI:</b> <b>59079968R030103-FMV5</b>	Class IIa	<b>NEBULIZER with T F/M adaptor, mouthpiece, corrugated tube and tubing</b>	DD 1023663-1 NB 0197
<b>NEBULIZER mask with tubing</b>  <b>Basic UDI-DI:</b> <b>59079968R030103-MMN</b>	Class IIa	<b>NEBULIZER with mask and tubing</b>	DD 1023663-1 NB 0197

Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)	MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)	Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas	MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas
<b>OXYGEN MASK with tubing</b>  Basic UDI-DI: 59079968R03010201L4	Class IIa	OXYGEN MASK with tubing	DD 1023663-1 NB 0197
<b>NON-REBREATHER MASK with tubing</b>  Basic UDI-DI: 59079968R03010206LE	Class IIa	NONREBREATHER MASK with tubing	DD 1023663-1 NB 0197
<b>VENTURI MASK with adjustable diluter and tubing</b>  Basic UDI-DI: 59079968R03010202-AXK	Class IIa	VENTURI MASK with adjustable diluter and tubing	DD 1023663-1 NB 0197
<b>NASAL OXYGEN CANNULA for adults</b> <b>NASAL OXYGEN CANNULA for children</b> <b>NASAL OXYGEN CANNULA for infants</b>  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
<b>SUCTION CATHETER</b> <b>SUCTION CATHETER IDEAL</b> <b>SUCTION CATHETER with vacuum control</b> <b>SUCTION CATHETER with vacuum control IDEAL</b>  Basic UDI-DI: 59079968R0501QP	Class IIa	SUCTION CATHETER 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>  Basic UDI-DI: 59079968U010201-LRXH	Class IIa	TWO-WAY FOLEY CATHETER with rubber valve	DD 1023663-1 NB 0197
<b>Two-way Foley catheter with plastic valve (silicone-coated latex)</b>  Basic UDI-DI: 59079968U010201-LPXD	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>	Class IIa	TWO-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197
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<b>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
<b>Basic UDI-DI: 59079968U010201-SP6</b>			
<b>Three-way Foley catheter with plastic valve (silicone-coated latex)</b>	Class IIa	THREE-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197
<b>Basic UDI-DI: 59079968U010201-3LUV</b>			
<b>Three-way Foley catheter with plastic valve (100% silicone, X-ray contrast)</b>	Class IIa	THREE-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197
<b>Basic UDI-DI: 59079968U010201-3SVB</b>			
<b>Two-way Foley catheter with plastic valve, Tiemann tip (silicone-coated latex)</b>	Class IIa	TWO-WAY FOLEY CATHETER with plastic valve, Tiemann tip	DD 1023663-1 NB 0197
<b>Basic UDI-DI: 59079968U0102R6</b>			
<b>TIEMANN CATHETER</b>	Class IIa	TIEMANN CATHETER	DD 1023663-1 NB 0197
<b>Basic UDI-DI: 59079968U010106HB</b>			
<b>PEZZER CATHETER</b>	Class IIa	PEZZER CATHETER	DD 1023663-1 NB 0197
<b>Basic UDI-DI: 59079968U010107HD</b>			
<b>FEEDING TUBE</b>	Class IIa	FEEDING TUBE	DD 1023663-1 NB 0197
<b>Basic UDI-DI: 59079968G02020101BU</b>			
<b>STOMACH TUBE DUODENAL TUBE</b>	Class IIa	STOMACH TUBE DUODENAL TUBE	DD 1023663-1 NB 0197
<b>Basic UDI-DI: 59079968G020201A3</b>			

<b>SUCTION CANNULA with suction control</b> <b>SUCTION CANNULA without suction control</b>  <b>Basic UDI-DI:</b> <b>59079968A06010184</b>	Class IIa	SUCTION CANNULA with suction control SUCTION CANNULA without suction control	DD 1023663-1 NB 0197
<b>SUCTION CANNULA with suction control, ball tip</b> <b>SUCTION CANNULA without suction control, ball tip</b>  <b>Basic UDI-DI:</b> <b>59079968A060101-BA2</b>	Class IIa	SUCTION CANNULA with suction control, ball tip SUCTION CANNULA without suction control, ball tip	DD 1023663-1 NB 0197

<b>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
<b>SURGICAL SUCTION SET with suction control, Yankauer tip</b> <b>SURGICAL SUCTION SET without suction control, Yankauer tip</b>  <b>Basic UDI-DI:</b> <b>59079968A060101039F</b>	Class IIa	SURGICAL SUCTION SET with suction control, Yankauer tip SURGICAL SUCTION SET without suction control, Yankauer tip	DD 1023663-1 NB 0197
<b>SURGICAL SUCTION SET with suction control, funnel-funnel cut-to-fit, Yankauer tip</b> <b>SURGICAL SUCTION SET without suction control, funnel-funnel cut-to-fit, Yankauer tip</b>  <b>Basic UDI-DI:</b> <b>59079968A06010103FFUC</b>	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

<b>SURGICAL SUCTION SET with suction control, funnel-funnel cut-to-fit, ball tip</b> <b>SURGICAL SUCTION SET without suction control, funnel-funnel cut-to-fit, ball tip</b>  <b>Basic UDI-DI: 59079968A06010103-FFB6J</b>	Class IIa	<b>SURGICAL SUCTION SET with suction control, funnel-funnel cut-to-fit, ball tip</b> <b>SURGICAL SUCTION SET without suction control, funnel-funnel cut-to-fit, ball tip</b>	DD 1023663-1 NB 0197
<b>SUCTION TUBE funnel-funnel</b>  <b>Basic UDI-DI: 59079968A060304-FFG4</b>	Class IIa	<b>SUCTION TUBE funnel-funnel</b>	DD 1023663-1 NB 0197
<b>SUCTION TUBE funnel-funnel cut-to-fit</b>  <b>Basic UDI-DI: 59079968A060304-FCFW</b>	Class IIa	<b>SUCTION TUBE funnel-funnel cut-to-fit</b>	DD 1023663-1 NB 0197
<b>SUCTION TUBE funnel-Kapkon</b>  <b>Basic UDI-DI: 59079968A060304-FKGE</b>	Class IIa	<b>SUCTION TUBE funnel-Kapkon</b>	DD 1023663-1 NB 0197
<b>easyWAY Three-way stopcock</b>	Class IIa	<b>easyWAY Three-way stopcock</b>	DD 1023663-1 NB 0197

<b>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
<b>Basic UDI-DI: 59079968A0703KA</b> <b>easyWAY L Three-way stopcock with extension</b>  <b>Basic UDI-DI: 59079968A0703-LA4</b>	Class IIa	<b>easyWAY L Three-way stopcock with extension</b>	DD 1023663-1 NB 0197
<b>easyFLOW LINE Extension tube for infusion pump, phthalate-free</b>  <b>Basic UDI-DI: 59079968A03020178</b>	Class IIa	<b>easyFLOW LINE Extension tube for infusion pump, phthalate-free</b>	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, phthalatefree	DD 1023663-1 NB 0197
easyFLOW IS Infusion set easyFLOW IS ECO Infusion set  Basic UDI-DI: 59079968A03010103PHT6H	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, phthalatefree easyFLOW IS PREMIUM Infusion set, phthalatefree  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  Basic UDI-DI: 59079968A03010103-SG2	Class IIa	easyFLOW IS SAFE Safety infusion set, phthalate-free easyFLOW IS SAFE PREMIUM Safety infusion set, phthalate-free	DD 1023663-1 NB 0197
easyFLOW IS REG Infusion set with precision flow rate regulator, phthalate-free	Class IIa	easyFLOW IS REG Infusion set with precision flow rate	DD 1023663-1 NB 0197

Prietaiso pavadinimas arba bazinis UDI- DI (pagal MDR paraišką)	MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)	Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas	MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas
Basic UDI-DI: 59079968A03010103-RFY		regulator, phthalate- free	
easyFLOW IS AMBER Infusion set, amber, phthalate-free  Basic UDI-DI: 59079968A03010103-AEW	Class IIa	easyFLOW IS AMBER Infusion set, amber, phthalatefree	DD 1023663-1 NB 0197

<b>ENDOTRACHEAL TUBE UNCUFFED</b>  <b>Basic UDI-DI: 59079968R010301FQ</b>	Class IIa	ENDOTRACHEAL TUBE UNCUFFED	DD 1023663-1 NB 0197
<b>ENDOTRACHEAL TUBE CUFFED</b>  <b>Basic UDI-DI: 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: 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 BREATHING CIRCUIT FOR ADULTS with bag, expandable, additional arm</b>  <b>Basic UDI-DI: 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 BREATHING CIRCUIT FOR ADULTS</b>  <b>Basic UDI-DI: 59079968R0201Q8</b>	Class IIa	BREATHING CIRCUIT FOR CHILDREN BREATHING CIRCUIT FOR ADULTS	DD 1023663-1 NB 0197
<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>	Class IIa	CATHETER MOUNT with double swivel	DD 1023663-1 NB 0197

<b>Prietaiso pavadinimas arba bazinis UDI- DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
<b>Basic UDI-DI: 59079968R020202-ELT</b>		elbow connector, expandable	

<b>CATHETER MOUNT with double swivel elbow connector, corrugated</b>  <b>Basic UDI-DI:</b> <b>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:</b> <b>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:</b> <b>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:</b> <b>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:</b> <b>59079968R0202-SHP</b>	Class IIa	CATHETER MOUNT with elbow connector, smoothbore	DD 1023663-1 NB 0197
<b>CATHETER MOUNT with elbow connector, corrugated</b>  <b>Basic UDI-DI:</b> <b>59079968R0202-CGP</b>	Class IIa	CATHETER MOUNT with elbow connector, corrugated	DD 1023663-1 NB 0197
<b>CATHETER MOUNT with elbow connector, expandable</b>  <b>Basic UDI-DI:</b> <b>59079968R0202-EGT</b>	Class IIa	CATHETER MOUNT with elbow connector, expandable	DD 1023663-1 NB 0197
<b>TRACHEOSTOMY TUBE cuffed</b>  <b>Basic UDI-DI:</b> <b>59079968R010502G4</b>	Class IIa	TRACHEOSTOMY TUBE cuffed	DD 1023663-1 NB 0197
<b>TRACHEOSTOMY TUBE uncuffed</b>	Class IIa	TRACHEOSTOMY TUBE uncuffed	DD 1023663-1 NB 0197

<b>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
<b>Basic UDI-DI: 59079968R010501G2</b>			
<b>LARYNGEAL MASK, PVC, disposable</b>  <b>Basic UDI-DI: 59079968R0102-PH6</b>	Class IIa	LARYNGEAL MASK, PVC, disposable	DD 1023663-1 NB 0197
<b>LARYNGEAL MASK, silicone, disposable</b>  <b>Basic UDI-DI: 59079968R0102-SHC</b>	Class IIa	LARYNGEAL MASK, silicone, disposable	DD 1023663-1 NB 0197
<b>AIR CUSHION ANAESTHETIC MASK</b>  <b>Basic UDI-DI: 59079968R030101-CLQ</b>	Class IIa	AIR CUSHION ANAESTHETIC MASK	DD 1023663-1 NB 0197
<b>ANAESTHETIC MASK with open seal</b>  <b>Basic UDI-DI: 59079968R030101-OMG</b>	Class IIa	ANAESTHETIC MASK with open seal	DD 1023663-1 NB 0197
<b>duoNEX Single use syringe, 2-part</b>  <b>Basic UDI-DI: 59079968A0201020101DK</b>	Class IIa	duoNEX Single use syringe, 2-part	DD 1023663-1 NB 0197
<b>dicoNEX Single use syringe, 3-part (luer)</b>  <b>Basic UDI-DI: 59079968A0201020102DM</b>	Class IIa	dicoNEX Single use syringe, 3-part (luer)	DD 1023663-1 NB 0197
<b>Apteczka ABC Strzykawka 3-częściowa</b>  <b>Basic UDI-DI: 59079968A0201020102DM</b>	Class IIa	Apteczka ABC Strzykawka 3częściowa	DD 1023663-1 NB 0197
<b>dicoNEX Single use syringe, 3-part (luer lock)</b>  <b>Basic UDI-DI: 59079968A0201020201DQ</b>	Class IIa	dicoNEX Single use syringe, 3-part (luer lock)	DD 1023663-1 NB 0197

dicoNEX Single use amber syringe, 3-part (luer lock)  Basic UDI-DI: 59079968A0201020201AVY	Class IIa	dicoNEX Single use amber syringe, 3-part (luer lock)	DD 1023663-1 NB 0197
dicoNEX	Class IIa	dicoNEX	DD 1023663-1 NB 0197

Prietaiso pavadinimas arba bazinis UDI- DI (pagal MDR paraišką)	MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)	Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas	MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas
Single use catheter syringe, 3-part  Basic UDI-DI: 59079968A020102037G		Single use catheter syringe, 3-part	
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, 3piece, 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: 59079968A0201020201IWG	Class IIa	dicoNEX MN Single use syringe, 3-piece with mounted needle (luer lock) dicoNEX SN Single use syringe, 3piece, 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: 59079968A0201020201IA9D	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  Basic UDI-DI: 59079968A02010978	Class IIa	dicoTUBER Tuberculin syringe	DD 1023663-1 NB 0197
dispoFINE Injection needle	Class IIa	dispoFINE Injection needle	DD 1023663-1 NB 0197

Prietaiso pavadinimas arba bazinis UDI- DI (pagal MDR paraišką)	MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)	Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas	MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas
Basic UDI-DI: 59079968A0101010102CK			
dispoGUARD Safety injection needle  Basic UDI-DI: 59079968A0101010101CH	Class IIa	dispoGUARD Safety injection needle	DD 1023663-1 NB 0197
dispoSULIN Insulin pen needle  Basic UDI-DI: 59079968A010101026Q	Class IIa	dispoSULIN Insulin pen needle	DD 1023663-1 NB 0197
easyFLOW TS Transfusion set  Basic UDI-DI: 59079968A03010102- PHT66	Class IIa	easyFLOW TS Transfusion set	DD 1023663-1 NB 0197
easyFLOW TS Transfusion set, phthalate-free easyFLOW TS PREMIUM Transfusion set, phthalate-free  Basic UDI-DI: 59079968A030101027S	Class IIa	easyFLOW TS Transfusion set, phthalate-free easyFLOW TS PREMIUM Transfusion set, phthalate-free	DD 1023663-1 NB 0197
NEEDLE FREE VALVE blue  Basic UDI-DI: 59079968A0705KE	Class IIa	NEEDLE FREE VALVE blue	DD 1023663-1 NB 0197

<b>NEEDLE FREE VALVE transparent</b>  <b>Basic UDI-DI:</b> <b>59079968A07050295</b>	Class IIa	NEEDLE FREE VALVE transparent	DD 1023663-1 NB 0197
<b>NEEDLE FREE VALVE transparent with extension line, single</b> <b>NEEDLE FREE VALVE transparent with extension line, double</b> <b>NEEDLE FREE VALVE transparent with extension line, triple</b> <b>NEEDLE FREE VALVE transparent with extension line, quadruple</b>  <b>Basic UDI-DI:</b> <b>59079968A070502-LCQ</b>	Class IIa	NEEDLE FREE VALVE transparent with extension line, single NEEDLE FREE VALVE transparent with extension line, double NEEDLE FREE VALVE transparent with extension line, triple NEEDLE FREE VALVE transparent with extension line, quadruple	DD 1023663-1 NB 0197

<b>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
<b>safeCARE Surgical gloves, latex, powdered</b>  <b>Basic UDI-DI:</b> <b>59079968T01010101-RYM</b>	Class IIa	safeCARE Surgical gloves, latex, powdered	DD 1023663-1 NB 0197
<b>safeCARE PF Surgical gloves powder free, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968T01010102-RYS</b>	Class IIa	safeCARE PF Surgical gloves powder free, sterile	DD 1023663-1 NB 0197
<b>safeCARE basic Surgical gloves latex, powdered</b>  <b>Basic UDI-DI:</b> <b>59079968T01010101-RYM</b>	Class IIa	safeCARE basic Surgical gloves latex, powdered	DD 1023663-1 NB 0197
<b>safeCARE basic PF Surgical gloves latex, powder-free</b>  <b>Basic UDI-DI:</b> <b>59079968T01010102-RYS</b>	Class IIa	safeCARE basic PF Surgical gloves latex, powder-free	DD 1023663-1 NB 0197

<b>safeCARE premium Surgical gloves latex, powder-free safeCARE UG Surgical gloves latex, powder-free safeCARE micro Surgical gloves latex, powder-free safeCARE ortho Surgical gloves latex, powder-free safeCARE dual Surgical gloves latex, powder-free</b>  <b>Basic UDI-DI:</b> <b>59079968T010102-RYS</b>	Class IIa	safeCARE premium Surgical gloves latex, powder-free safeCARE UG Surgical gloves latex, powder-free safeCARE micro Surgical gloves latex, powder-free safeCARE ortho Surgical gloves latex, powder-free safeCARE dual Surgical gloves latex, powder-free	DD 1023663-1 NB 0197
<b>safeCARE synthetic Surgical gloves neoprene, powder-free safeCARE synthetic UG Surgical gloves neoprene, powder-free</b>  <b>Basic UDI-DI:</b> <b>59079968T010102-NRWL</b>	Class IIa	safeCARE synthetic Surgical gloves neoprene, powder-free safeCARE synthetic UG Surgical gloves neoprene, powderfree	DD 1023663-1 NB 0197
<b>safeCARE fusion Surgical gloves polyisoprene, powderfree</b>	Class IIa	safeCARE fusion Surgical gloves polyisoprene, powder-free	DD 1023663-1 NB 0197

<b>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB identifikavimas</b>
<b>Basic UDI-DI:</b> <b>59079968T010102-PRWS</b>			
<b>safeCARE virtuo Surgical gloves flexylon, powderfree safeCARE virtuo UG Surgical gloves flexylon, powder-free safeCARE pro protect Surgical gloves flexylon, powder-free</b>  <b>Basic UDI-DI:</b> <b>59079968T010102-FRVU</b>	Class IIa	safeCARE virtuo Surgical gloves flexylon, powderfree safeCARE virtuo UG Surgical gloves flexylon, powderfree safeCARE pro protect Surgical gloves flexylon, powder-free	DD 1023663-1 NB 0197

<b>safeLANCE</b> <b>Pressure-activated safety</b> <b>lancet</b>	Class IIa	safeLANCE Pressure-activated safety lancet	DD 1023663-1 NB 0197
<b>Basic UDI-DI:</b> <b>59079968V0104RM</b>			
<b>deltaset</b> <b>Procedure kit O</b>	Class IIa	deltaset Urinary bladder catheterization kit	DD 1023663-1 NB 0197
<b>Basic UDI-DI:</b> <b>59079968V0599-SETA</b>			
<b>deltaset</b> <b>Procedure kit O</b>	Class IIa	deltaset Urinary bladder catheterization kit	DD 1023663-1 NB 0197
<b>Basic UDI-DI:</b> <b>59079968V0599-SHTG</b>			
<b>deltaset</b> <b>Procedure kit O</b>	Class IIa	deltaset Dialysis kit	DD 1023663-1 NB 0197
<b>Basic UDI-DI:</b> <b>59079968V0599-CERS</b>			
<b>deltaset</b> <b>Procedure kit O</b>	Class IIa	deltaset Dialysis kit	DD 1023663-1 NB 0197
<b>Basic UDI-DI:</b> <b>59079968V0599-CHRY</b>			
<b>deltaset</b> <b>Procedure kit O</b>	Class IIa	deltaset Dressing change kit	DD 1023663-1 NB 0197
<b>Basic UDI-DI:</b> <b>59079968V0599-WETN</b>			
<b>deltaset</b> <b>Procedure kit O</b>	Class IIa	deltaset Dressing change kit	DD 1023663-1 NB 0197
<b>Basic UDI-DI:</b> <b>59079968V0599-WHTU</b>			
<b>deltaset</b> <b>Procedure kit O</b>	Class IIa	deltaset Suture application kit	DD 1023663-1 NB 0197

<b>Prietaiso pavadinimas</b> <b>arba bazinis UDI-</b> <b>DI (pagal MDR</b> <b>paraišką)</b>	<b>MDR prietaiso</b> <b>klasifikacija</b> <b>(kaip pasiūlė</b> <b>gamintojas ir</b> <b>patikrinta prieš</b> <b>paraišką)</b>	<b>Jei MDR</b> <b>prietaisas yra</b> <b>pakaitalas,</b> <b>atitinkamo</b> <b>MDD/AIMDD</b> <b>prietaiso</b> <b>identifikavimas</b>	<b>MDD / AIMDD</b> <b>sertifikato</b> <b>nuoroda</b> <b>prietaisams</b> <b>pagal MDR</b> <b>paraišką ir NB</b> <b>Identifikavimas</b>
<b>Basic UDI-DI:</b> <b>59079968V0599-RET7</b>		deltaset Suture removal kit	

<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 Nonwoven dressing with absorbent pad, selfadhesive, sterile</b> <b>elastoKIDS STERIL Nonwoven dressing with absorbent pad, selfadhesive, sterile</b>  <b>Basic UDI-DI: 59079968T0305RB</b>	Class I devices placed on the market in sterile condition	elastopor STERIL Non-woven dressing with absorbent pad, self-adhesive, sterile elastoKIDS STERIL Nonwoven dressing with absorbent pad, self-adhesive, sterile	DD 1023663-1 NB 0197
<b>elastoDERM PAD Foil dressing, with absorbent pad, selfadhesive, sterile</b>  <b>Basic UDI-DI: 59079968M040101-FHU</b>	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
<b>elastoSTRIP Wound closure strips, sterile</b>  <b>Basic UDI-DI: 59079968M040499FL</b>	Class I devices placed on the market in sterile condition	elastoSTRIP Wound closure strips, sterile	DD 1023663-1 NB 0197
<b>UMBILICAL CORD CLAMP, sterile</b>  <b>Basic UDI-DI: 59079968V0202RN</b>	Class I devices placed on the market in sterile condition	UMBILICAL CORD CLAMP, sterile	DD 1023663-1 NB 0197
<b>ALPHAtex Procedure gown NORMAL, sterile</b>	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown NORMAL, sterile	DD 1023663-1 NB 0197

Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)	MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)	Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas	MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas
<b>Basic UDI-DI: 59079968T0205R6</b>			
<b>ALPHAtex Procedure gown NORMAL-P</b>  <b>Basic UDI-DI: 59079968T0205R6</b>	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown NORMAL-P, sterile	HD 1023663-1 NB 0197
<b>ALPHAtex Surgical gown STANDARD, sterile</b> <b>ALPHAtex Surgical gown COMFORT sterile</b>  <b>Basic UDI-DI: 59079968T020401HA</b>	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
<b>ALPHAtex Surgical gown CLASSIC-P</b> <b>ALPHAtex Surgical gown STANDARD-P</b> <b>ALPHAtex Surgical gown COMFORT-P</b>  <b>Basic UDI-DI: 59079968T020401HA</b>	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
<b>ALPHAtex Surgical gown STANDARD PLUS, with impermeable parts, sterile</b> <b>ALPHAtex Surgical gown COMFORT PLUS, with impermeable parts, sterile</b> <b>ALPHAtex Surgical gown EXTRA SAFE, with impermeable parts, sterile</b>  <b>Basic UDI-DI: 59079968T020402HC</b>	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

<b>ALPHAtex Surgical gown STANDARD PLUS-P, with impermeable parts</b> <b>ALPHAtex Surgical gown COMFORT PLUS-P, with impermeable parts</b> <b>ALPHAtex Surgical gown EXTRA SAFE-P, with impermeable parts</b>  <b>Basic UDI-DI: 59079968T020402HC</b>	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	HD 1023663-1 NB 0197
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<b>Prietaiso pavadinimas arba bazinis UDI- DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
		impermeable parts, sterile	

<b>ALPHAtex Surgical drape, sterile</b> <b>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 central adhesive fenestration, sterile ALPHAtex Reinforced surgical drape with adhesive fenestration, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968T0201QW</b>	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, 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 central, adjustable adhesive fenestration, sterile ALPHAtex Reinforced surgical drape with adhesive fenestration, sterile	DD 1023663-1 NB 0197
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<b>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
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<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>  <b>Basic UDI-DI:</b> <b>59079968T0201QW</b>	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
<b>ALPHAtex Instrument table cover, sterile</b>  <b>Basic UDI-DI:</b> <b>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:</b> <b>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>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
<b>ALPHAtex Armboard cover, sterile</b> <b>ALPHAtex Surgical pocket for syringes, sterile</b>  <b>Basic UDI-DI:</b> <b>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:</b> <b>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:</b> <b>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> <b>ALPHAtex Absorbent drape for newborn, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968T020199-SRU</b>	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
<b>ALPHAtex Limb cover, sterile</b> <b>ALPHAtex Head Turban drape, sterile</b> <b>ALPHAtex Under buttocks drape, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968T020102GV</b>	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

<b>ALPHAtex Adhesive pouch, one-chamber, sterile</b>	Class I devices placed on the	ALPHAtex Adhesive pouch,	DD 1023663-1 NB 0197
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<b>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
<b>ALPHAtex Adhesive pouch, two-chamber, sterile</b> <b>ALPHAtex Arthroscopy fluid collection pouch, cone-shaped, with outlet tip, sterile</b> <b>ALPHAtex Fluid collection pouch, coneshaped, with outlet tip, sterile</b>  <b>Basic UDI-DI: 59079968T020199-PRN</b>	market in sterile condition	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	
<b>ALPHAtex Non-woven surgical tape, adhesive, sterile</b> <b>ALPHAtex Velcro surgical tape, sterile</b>  <b>Basic UDI-DI: 59079968T020199-TRW</b>	Class I devices placed on the market in sterile condition	ALPHAtex Nonwoven surgical tape, adhesive, sterile ALPHAtex Velcro surgical tape, sterile	DD 1023663-1 NB 0197

<b>ALPHAtex Abdominal drape, sterile</b> <b>ALPHAtex Abdo-Perineal drape, sterile</b> <b>ALPHAtex Angiography drape, sterile</b> <b>ALPHAtex Cardiology drape, sterile</b> <b>ALPHAtex Cardiac drape, sterile</b> <b>ALPHAtex C-section drape, sterile</b> <b>ALPHAtex Delivery drape, sterile</b> <b>ALPHAtex Extremity drape, sterile</b> <b>ALPHAtex Gynaecology drape, sterile</b> <b>ALPHAtex Laparoscopy drape, sterile</b> <b>ALPHAtex Ophthalmic drape, sterile</b> <b>ALPHAtex Orthopaedic drape, sterile</b> <b>ALPHAtex Shoulder drape, sterile</b> <b>ALPHAtex Vertical isolation drape, sterile</b>	Class I devices placed on the market in sterile condition	ALPHAtex Abdominal drape, sterile ALPHAtex AbdoPerineal 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	DD 1023663-1 NB 0197
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<b>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
		ALPHAtex Vertical isolation drape (from 1 to 100)	

<b>ALPHAtex Abdominal set, sterile</b> <b>ALPHAtex Abdo-Perineal set, sterile</b> <b>ALPHAtex Ablation set, sterile</b> <b>ALPHAtex Angiography set, sterile</b> <b>ALPHAtex Arthroscopy set, sterile</b> <b>ALPHAtex Basic set, sterile</b> <b>ALPHAtex Cardiology set, sterile</b> <b>ALPHAtex Cardiac set, sterile</b> <b>ALPHAtex Craniotomy set, sterile</b> <b>ALPHAtex C-section set, sterile</b> <b>ALPHAtex Cystoscopy set, sterile</b> <b>ALPHAtex Delivery set, sterile</b> <b>ALPHAtex Dental set, sterile</b> <b>ALPHAtex Dynamic hip screw set, sterile</b> <b>ALPHAtex Extremity set, sterile</b> <b>ALPHAtex Gynaecology set, sterile</b> <b>ALPHAtex Hip set, sterile</b> <b>ALPHAtex Laparoscopy set, sterile</b> <b>ALPHAtex Laryngology set, sterile</b> <b>ALPHAtex Ophthalmic set, sterile</b> <b>ALPHAtex Otolaryngology set, sterile</b> <b>ALPHAtex Pediatric set, sterile</b> <b>ALPHAtex Percutaneous lithotripsy set, sterile</b> <b>ALPHAtex Shoulder set, sterile</b> <b>ALPHAtex Spine set, sterile</b>	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 C-section set, sterile ALPHAtex Cystoscopy 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	DD 1023663-1 NB 0197
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<b>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
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<b>ALPHAtex Thyroid set, sterile</b> <b>ALPHAtex TUR set, sterile</b> <b>ALPHAtex Universal set, sterile</b> <b>ALPHAtex Uro/gynaecology set, sterile</b> <b>ALPHAtex Varicose vein set, sterile</b> <b>ALPHAtex Vertical isolation set, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968T0202QY</b>		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	
<b>ALPHAtex Abdominal set, sterile</b> <b>ALPHAtex Abdo-Perineal set, sterile</b> <b>ALPHAtex Ablation set, sterile</b> <b>ALPHAtex Angiography set, sterile</b> <b>ALPHAtex Arthroscopy set, sterile</b> <b>ALPHAtex Basic set, sterile</b> <b>ALPHAtex Cardiology set, sterile</b> <b>ALPHAtex Cardiac set, sterile</b> <b>ALPHAtex Craniotomy set, sterile</b> <b>ALPHAtex C-section set, sterile</b>	Class I devices placed on the market in sterile condition	"ALPHAtex Abdominal set (from 1 to 200) ALPHAtex Abdo-Perineal set (from 1 to 200) ALPHAtex Ablation set (from 1 to 200) ALPHAtex Angiography set (from 1 to 200) ALPHAtex Arthroscopy set (from 1 to 200) ALPHAtex Basic set (from 1 to 200) ALPHAtex Cardiology set (from 1 to 200)	HD 1023663-1 NB 0197

Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)	MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)	Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas	MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas
<p>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 Varicose vein set, sterile  ALPHAtex Vertical isolation set, sterile</p> <p>Basic UDI-DI:  59079968T0202QY</p>		<p>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)  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)</p>	

Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)	MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)	Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas	MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas
		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)"	
<b>elastoLUMENAL S Eye pad, superabsorbent, multi-layer, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M040301-SKC</b>	Class I devices placed on the market in sterile condition	elastoLUMENAL S Eye pad, superabsorbent, multi-layer, sterile	DD 1023663-1 NB 0197
<b>elastopor EYE Eye dressing, non-woven, with absorbent pad, selfadhesive, sterile</b> <b>elastoKIDS EYE Eye dressing, non-woven, with absorbent pad, selfadhesive, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M0403NX</b>	Class I devices placed on the market in sterile condition	lastopor EYE Eye dressing, nonwoven, with absorbent pad, self-adhesive, sterile elastoKIDS EYE Eye dressing, nonwoven, with absorbent pad, self-adhesive, sterile	DD 1023663-1 NB 0197
<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 Nonwoven dressing with absorbent pad, with incision and O-hole, selfadhesive, sterile elastoKIDS STERIL D Non-woven dressing, with absorbent pad, with</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, selfadhesive, sterile elastopor STERIL D Non-woven	DD 1023663-1 NB 0197
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<b>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
incision and X-hole, selfadhesive, sterile  <b>Basic UDI-DI:</b> <b>59079968M04010201-DTG</b>		dressing, with absorbent pad, with incision and Xhole, self-adhesive, sterile elastoKIDS STERIL D Nonwoven dressing, with absorbent pad, with incision and X-hole, selfadhesive, sterile	
<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 Nonwoven swab, with O-incision, sterile NONVI lux S Nonwoven swab, with Y-incision, sterile	DD 1023663-1 NB 0197
<b>elastopor IV IV cannula dressing, non-woven, selfadhesive, sterile 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

<b>elastoDERM F-IV IV cannula dressing, foil, with frame, with Uincision, 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</b>  <b>Basic UDI-DI:</b> <b>59079968M04010202H4</b>	Class I devices placed on the market in sterile condition	elastoDERM F-IV IV cannula dressing, foil, with frame, with Uincision, selfadhesive, sterile elastoDERM IV IV cannula dressing, foil, selfadhesive, sterile elastoDERM Foil dressing, selfadhesive, sterile elastoDERM F Foil dressing, with frame, selfadhesive, sterile elastoDERM C Foil dressing with a pocket to secure catheter, sterile	DD 1023663-1 NB 0197
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<b>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
<b>MULTIabsorb S ABD pad, non-woven and cellulose, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M040201-SJZ</b>	Class I devices placed on the market in sterile condition	MULTIabsorb S ABD pad, nonwoven and cellulose, sterile	DD 1023663-1 NB 0197
<b>VAGINAL SPECULUM</b>  <b>Basic UDI-DI:</b> <b>59079968U089006MJ</b>	Class I devices placed on the market in sterile condition	VAGINAL SPECULUM	DD 1023663-1 NB 0197
<b>URINE BAG</b>  <b>Basic UDI-DI:</b> <b>59079968A0603038J</b>	Class I devices placed on the market in sterile condition	URINE BAG	DD 1023663-1 NB 0197
<b>URINE BAG with sample port, sterile</b> <b>URINE BAG with sample port 2W, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968A060303-PBW</b>	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

<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> <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>  <b>Basic UDI-DI:</b> <b>59079968A06030301AB</b>	Class I devices placed on the market in sterile condition	<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> <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>	DD 1023663-1 NB 0197
<b>ENEMA BAG sterile</b>  <b>Basic UDI-DI:</b> <b>59079968G020301-SDY</b>	Class I devices placed on the market in sterile condition	<b>ENEMA BAG sterile</b>	DD 1023663-1 NB 0197

<b>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
<b>WOODEN TONGUE DEPRESSOR Sterile</b>  <b>Basic UDI-DI:</b> <b>59079968V9001-SNM</b>	Class I devices placed on the market in sterile condition	<b>WOODEN TONGUE DEPRESSOR sterile</b>	DD 1023663-1 NB 0197
<b>NELATON CATHETER NELATON CATHETER transparent</b>  <b>Basic UDI-DI:</b> <b>59079968U010105H9</b>	Class I devices placed on the market in sterile condition	<b>NELATON CATHETER NELATON CATHETER transparent</b>	DD 1023663-1 NB 0197
<b>GUEDEL AIRWAY</b>  <b>Basic UDI-DI:</b> <b>59079968R010102FG</b>	Class I devices placed on the market in sterile condition	<b>GUEDEL AIRWAY</b>	DD 1023663-1 NB 0197

<b>ENDOTRACHEAL TUBE HOLDER, vertical fixation</b> <b>ENDOTRACHEAL TUBE HOLDER, horizontal fixation</b>  <b>Basic UDI-DI:</b> <b>59079968R010380-SNX</b>	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
<b>INTUBATION STYLET TRACHEAL TUBE INTRODUCER CURVED</b>  <b>Basic UDI-DI:</b> <b>59079968R010380-PNR</b>	Class I devices placed on the market in sterile condition	INTUBATION STYLET TRACHEAL TUBE INTRODUCER CURVED	DD 1023663-1 NB 0197
<b>dicoSPIKE Withdrawal cannula with bacteria filter</b> <b>dicoSPIKE Withdrawal cannula with bacteria and particle filter</b> <b>dicoSPIKE Chemo Withdrawal cannula with bacteria and particle filter</b>  <b>Basic UDI-DI:</b> <b>59079968A0704KC</b>	Class I devices placed on the market in sterile condition	dicoSPIKE Withdrawal cannula with bacteria filter dicoSPIKE Withdrawal cannula with bacteria and particle filter dicoSPIKE Chemo Withdrawal cannula with bacteria and particle filter	DD 1023663-1 NB 0197
<b>elastoBAND BASIC S Knitted supporting bandage, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968M030301-SJT</b>	Class I devices placed on the market in sterile condition	elastoBAND BASIC S Knitted supporting bandage, sterile	HD 1023663-1 NB 0197
<b>elastoBAND FLEX S Elastic bandage, sterile</b>	Class I devices placed on the	elastoBAND FLEX S	DD 1023663-1 NB 0197

<b>Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
<b>Basic UDI-DI:</b> <b>59079968M030402-SKB</b>	market in sterile condition	Elastic bandage, sterile	

<b>elastoFILM Incise film, self-adhesive, sterile</b> <b>elastoFILM M Incise film, self-adhesive, sterile</b>  <b>Basic UDI-DI:</b> <b>59079968T020101GT</b>	Class I devices placed on the market in sterile condition	elastoFILM Incise film, self-adhesive, sterile elastoFILM M Incise film, selfadhesive, sterile	DD 1023663-1 NB 0197
<b>CERVICAL BRUSH standard</b> <b>CERVICAL BRUSH special</b>  <b>Basic UDI-DI:</b> <b>59079968U090303L7</b>	Class I devices placed on the market in sterile condition	CERVICAL BRUSH standard CERVICAL BRUSH special	DD 1023663-1 NB 0197
<b>omegapack Surgical set B</b>  <b>Basic UDI-DI:</b> <b>59079968V0599-EP2</b>	Class IIb excluding Class IIb implantable non-WET	omegapack Surgical set B Orthopedic surgery set B Universal set B Surgical set B Orthopedic surgery set B Universal set B	HD 1023663-1 NB 0197
<b>omegapack Surgical set B</b>  <b>Basic UDI-DI:</b> <b>59079968V0599-KPE</b>	Class IIb excluding Class IIb implantable non-WET	omegapack Surgical set B Orthopedic surgery set B Universal set B Surgical set B Orthopedic surgery set B Universal set B	HD 1023663-1 NB 0197
<b>omegapack Surgical set</b>  <b>Basic UDI-DI:</b> <b>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	HD 1023663-1 NB 0197

Prietaiso pavadinimas arba bazinis UDI-DI (pagal MDR paraišką)	MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)	Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas	MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas
		Universal set	
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  Basic UDI-DI: 59079968V0599-RPU	Class IIa	deltaset  Sewing kit Suture removal kit Dressing change kit	HD 1023663-1 NB 0197
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

<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
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<b>Prietaiso pavadinimas arba bazinis UDI- DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
<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 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

2 lentelė. Prietaisai, kuriems taikomas šis raštas ir už kuriuos NB NĖRA atsakinga už tinkamą atitinkamų prietaisų priežiūrą pagal taikomą direktyvą:

<b>Prietaiso pavadinimas arba bazinis UDI- DI (pagal MDR paraišką)</b>	<b>MDR prietaiso klasifikacija (kaip pasiūlė gamintojas ir patikrinta prieš paraišką)</b>	<b>Jei MDR prietaisas yra pakaitalas, atitinkamo MDD/AIMDD prietaiso identifikavimas</b>	<b>MDD / AIMDD sertifikato nuoroda prietaisams pagal MDR paraišką ir NB Identifikavimas</b>
nėra			

#### Patvirtinimo laiško peržiūros istorija

Data	NB vidinė nuoroda, atsekama į kiekvieną laiško versiją	Veiksmas
2024/05/15	ZARYS_CL607_202405- 15	Pradinis leidimas

Už vertimą atsakingas: A. Zapalskio IĮ „AZAS“ direktorius Juozas Devižis