

Verslo srities produktų
Sertifikavimo departamentas

TÜV Rheinland LGA Products GmbH 51105 Kiolnas

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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

GAZA lux Dressing gauze, nonsterile Basic UDI-DI: 59079968M020107DG	Class IIa	GAZA lux Dressing gauze, non-sterile	DD 1023663-1 NB 0197
KOMPRI lux S	Class IIa	KOMPRI lux S	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
Gauze swabs without Xray thread, sterile Basic UDI-DI: 59079968M02010201-ES4		Gauze swabs without X-ray thread, sterile	
KOMPRI lux S Gauze swabs without Xray thread, sterile Basic UDI-DI: 59079968M02010201-SSY	Class IIa	KOMPRI lux S Gauze swabs without X-ray thread, sterile	DD 1023663-1 NB 0197
KOMPRI lux S Gauze swabs with X-ray thread, sterile Basic UDI-DI: 59079968M02010202-ES9	Class IIa	KOMPRI lux S Gauze swabs with X-ray thread, sterile	DD 1023663-1 NB 0197
KOMPRI lux S Gauze swabs with X-ray thread, sterile Basic UDI-DI: 59079968M02010202-ST5	Class IIa	KOMPRI lux S Gauze swabs with X-ray thread, sterile	DD 1023663-1 NB 0197
KOMPRI lux Gauze swabs without Xray thread, non-sterile Basic UDI-DI: 59079968M02010201-NSN	Class IIa	KOMPRI lux Gauze swabs without X-ray thread, non-sterile	DD 1023663-1 NB 0197
KOMPRI lux Gauze swabs with X-ray thread, non-sterile Basic UDI-DI: 59079968M02010202-NST	Class IIa	KOMPRI lux Gauze swabs with X-ray thread, nonsterile	DD 1023663-1 NB 0197

SERVI lux S Gauze lap sponges with X-ray thread, sterile Basic UDI-DI: 59079968M02010302-ESL	Class IIa	SERVI lux S Gauze lap sponges with X-ray thread, sterile	DD 1023663-1 NB 0197
SERVI lux S Gauze lap sponges with X-ray thread, sterile Basic UDI-DI: 59079968M02010302-STG	Class IIa	SERVI lux S Gauze lap sponges with X-ray thread, sterile	DD 1023663-1 NB 0197
SERVI lux S Gauze lap sponges with X-ray chip, pre-washed, sterile	Class IIa	SERVI lux S Gauze lap sponges with X-ray chip, pre-washed, sterile	DD 1023663-1 NB 0197

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: 59079968M02010302PE86			
SERVI lux S Gauze lap sponges with X-ray chip, pre-washed, sterile Basic UDI-DI: 59079968M02010302PS92	Class IIa	SERVI lux S Gauze lap sponges with X-ray chip, pre-washed, sterile	DD 1023663-1 NB 0197
SERVI lux Gauze lap sponges with X-ray thread, non-sterile Basic UDI-DI: 59079968M02010302-NT6	Class IIa	SERVI lux Gauze lap sponges with X-ray thread, non- sterile	DD 1023663-1 NB 0197
SERVI lux Gauze lap sponges with X-ray chip, pre-washed, non-sterile Basic UDI-DI: 59079968M02010302PN8Q	Class IIa	SERVI lux Gauze lap sponges with X-ray chip, pre- washed, non- sterile	DD 1023663-1 NB 0197

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

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: 59079968M02010501-NTP			
TUPFER lux Gauze balls with X-ray thread, non-sterile Basic UDI-DI: 59079968M02010502-NTU	Class IIa	TUPFER lux Gauze balls with Xray thread, nonsterile	DD 1023663-1 NB 0197
SETON lux S Gauze rolls without X-ray thread, sterile Basic UDI-DI: 59079968M02010701-SUP	Class IIa	SETON lux S Gauze rolls without X-ray thread, sterile	DD 1023663-1 NB 0197
SETON lux S Gauze rolls with X-ray thread, sterile Basic UDI-DI:	Class IIa	SETON lux S Gauze rolls with Xray thread, sterile	DD 1023663-1 NB 0197

59079968M02010702-ETY			
SETON lux S Gauze rolls with X-ray thread, sterile Basic UDI-DI: 59079968M02010702-SUU	Class IIa	SETON lux S Gauze rolls with Xray thread, sterile	DD 1023663-1 NB 0197
SETON lux Gauze rolls without X-ray thread, non-sterile Basic UDI-DI: 59079968M02010701-NUD	Class IIa	SETON lux Gauze rolls without X-ray thread, nonsterile	DD 1023663-1 NB 0197
SETON lux Gauze rolls with X-ray thread, non-sterile Basic UDI-DI: 59079968M02010702-NUJ	Class IIa	SETON lux Gauze rolls with Xray thread, nonsterile	DD 1023663-1 NB 0197
NONVI lux S Non-woven swab, sterile Basic UDI-DI: 59079968M02020101-ESA	Class IIa	NONVI lux S Non- woven swabs, sterile	DD 1023663-1 NB 0197
NONVI lux S Non-woven swab, sterile Basic UDI-DI: 59079968M02020101-ST6	Class IIa	NONVI lux S Non- woven swabs, sterile	DD 1023663-1 NB 0197
NONVI lux S Non-woven swabs with Xray thread, sterile	Class IIa	NONVI lux S Non- woven swabs with X-ray thread, 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
Basic UDI-DI: 59079968M02020102-ESF			
NONVI lux S Non-woven swabs with Xray thread, sterile Basic UDI-DI: 59079968M02020102-STB	Class IIa	NONVI lux S Non- woven swabs with X-ray thread, sterile	DD 1023663-1 NB 0197

NONVI lux Non-woven swabs, non-sterile Basic UDI-DI: 59079968M02020101-NSU	Class IIa	NONVI lux Non-woven swabs, non-sterile	DD 1023663-1 NB 0197
NONVI lux Non-woven swabs with Xray thread, non-sterile Basic UDI-DI: 59079968M02020102-NSZ	Class IIa	NONVI lux Non-woven swabs with X-ray thread, non-sterile	DD 1023663-1 NB 0197
paraffiNET Paraffin gauze dressing, sterile Basic UDI-DI: 59079968M020302DG	Class IIa	paraffiNET Paraffin gauze dressing, sterile	DD 1023663-1 NB 0197
SANViflon I.V. cannula SANViflon S I.V. cannula without injection port SANViflon premium I.V. cannula SANViflon safe Safety I.V. cannula Basic UDI-DI: 59079968C0101017F	Class IIa	SANViflon I.V. cannula SANViflon S I.V. cannula without injection port SANViflon premium I.V. cannula SANViflon safe Safety I.V. cannula	DD 1023663-1 NB 0197
OXYGEN TUBING Basic UDI-DI: 59079968R03010204LA	Class IIa	OXYGEN TUBING	DD 1023663-1 NB 0197
NEBULIZER with T F/M adaptor, mouthpiece, corrugated tube and tubing Basic UDI-DI: 59079968R030103-FMV5	Class IIa	NEBULIZER with T F/M adaptor, mouthpiece, corrugated tube and tubing	DD 1023663-1 NB 0197
NEBULIZER mask with tubing Basic UDI-DI: 59079968R030103-MMN	Class IIa	NEBULIZER with mask and tubing	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
OXYGEN MASK with tubing Basic UDI-DI: 59079968R03010201L4	Class IIa	OXYGEN MASK with tubing	DD 1023663-1 NB 0197
NON-REBREATHER MASK with tubing Basic UDI-DI: 59079968R03010206LE	Class IIa	NONREBREATHER MASK with tubing	DD 1023663-1 NB 0197
VENTURI MASK with adjustable diluter and tubing Basic UDI-DI: 59079968R03010202-AXK	Class IIa	VENTURI MASK with adjustable diluter and tubing	DD 1023663-1 NB 0197
NASAL OXYGEN CANNULA for adults NASAL OXYGEN CANNULA for children NASAL OXYGEN CANNULA for infants Basic UDI-DI: 59079968R03010203L8	Class IIa	NASAL OXYGEN CANNULA for adults NASAL OXYGEN CANNULA for children NASAL OXYGEN CANNULA for infants	DD 1023663-1 NB 0197
SUCTION CATHETER SUCTION CATHETER IDEAL SUCTION CATHETER with vacuum control SUCTION CATHETER with vacuum control IDEAL 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
Two-way Foley catheter with rubber valve (silicone-coated latex) Basic UDI-DI: 59079968U010201-LRXH	Class IIa	TWO-WAY FOLEY CATHETER with rubber valve	DD 1023663-1 NB 0197
Two-way Foley catheter with plastic valve (silicone-coated latex) Basic UDI-DI: 59079968U010201-LPXD	Class IIa	TWO-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197

Two-way Foley catheter with plastic valve (100% silicone, X-ray contrast)	Class IIa	TWO-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197
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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: 59079968U010201-SP6			
Three-way Foley catheter with plastic valve (silicone-coated latex)	Class IIa	THREE-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197
Basic UDI-DI: 59079968U010201-3LUV			
Three-way Foley catheter with plastic valve (100% silicone, X-ray contrast)	Class IIa	THREE-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197
Basic UDI-DI: 59079968U010201-3SVB			
Two-way Foley catheter with plastic valve, Tiemann tip (silicone-coated latex)	Class IIa	TWO-WAY FOLEY CATHETER with plastic valve, Tiemann tip	DD 1023663-1 NB 0197
Basic UDI-DI: 59079968U0102R6			
TIEMANN CATHETER	Class IIa	TIEMANN CATHETER	DD 1023663-1 NB 0197
Basic UDI-DI: 59079968U010106HB			
PEZZER CATHETER	Class IIa	PEZZER CATHETER	DD 1023663-1 NB 0197
Basic UDI-DI: 59079968U010107HD			
FEEDING TUBE	Class IIa	FEEDING TUBE	DD 1023663-1 NB 0197
Basic UDI-DI: 59079968G02020101BU			
STOMACH TUBE DUODENAL TUBE	Class IIa	STOMACH TUBE DUODENAL TUBE	DD 1023663-1 NB 0197
Basic UDI-DI: 59079968G020201A3			

SUCTION CANNULA with suction control SUCTION CANNULA without suction control Basic UDI-DI: 59079968A06010184	Class IIa	SUCTION CANNULA with suction control SUCTION CANNULA without suction control	DD 1023663-1 NB 0197
SUCTION CANNULA with suction control, ball tip 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

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
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: 59079968A06010103FFUC	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, funnelfunnel cut-to-fit, ball tip SURGICAL SUCTION SET without suction control, funnelfunnel cut-to-fit, ball tip	DD 1023663-1 NB 0197
SUCTION TUBE funnelfunnel Basic UDI-DI: 59079968A060304-FFG4	Class IIa	SUCTION TUBE funnel-funnel	DD 1023663-1 NB 0197
SUCTION TUBE funnel-funnel cut-to-fit Basic UDI-DI: 59079968A060304-FCFW	Class IIa	SUCTION TUBE funnel-funnel cut-to-fit	DD 1023663-1 NB 0197
SUCTION TUBE funnel-Kapkon Basic UDI-DI: 59079968A060304-FKGE	Class IIa	SUCTION TUBE funnel-Kapkon	DD 1023663-1 NB 0197
easyWAY Three-way stopcock	Class IIa	easyWAY Three-way stopcock	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: 59079968A0703KA easyWAY L Three-way stopcock with extension Basic UDI-DI: 59079968A0703-LA4	Class IIa	easyWAY L Three-way stopcock with extension	DD 1023663-1 NB 0197
easyFLOW LINE Extension tube for infusion pump, phthalatefree Basic UDI-DI: 59079968A03020178	Class IIa	easyFLOW LINE Extension tube for infusion pump, phthalate-free	DD 1023663-1 NB 0197

easyFLOW LINE AMBER Extension tube for infusion pump, amber, phthalate-free Basic UDI-DI: 59079968A030201-A8Q	Class IIa	easyFLOW LINE AMBER Extension tube for infusion pump, amber, 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

ENDOTRACHEAL TUBE UNCUFFED Basic UDI-DI: 59079968R010301FQ	Class IIa	ENDOTRACHEAL TUBE UNCUFFED	DD 1023663-1 NB 0197
ENDOTRACHEAL TUBE CUFFED Basic UDI-DI: 59079968R010302FS	Class IIa	ENDOTRACHEAL TUBE CUFFED	DD 1023663-1 NB 0197
REINFORCED ENDOTRACHEAL TUBE CUFFED WITH PRELOADED STYLET Basic UDI-DI: 59079968R010302-RMF	Class IIa	REINFORCED ENDOTRACHEAL TUBE CUFFED WITH PRELOADED STYLET	DD 1023663-1 NB 0197
BREATHING CIRCUIT FOR CHILDREN with bag, expandable, additional arm BREATHING CIRCUIT FOR ADULTS with bag, expandable, additional arm Basic UDI-DI: 59079968R0201-BGG	Class IIa	BREATHING CIRCUIT FOR CHILDREN with bag, expandable, additional arm BREATHING CIRCUIT FOR ADULTS with bag, expandable, additional arm	DD 1023663-1 NB 0197
BREATHING CIRCUIT FOR CHILDREN BREATHING CIRCUIT FOR ADULTS Basic UDI-DI: 59079968R0201Q8	Class IIa	BREATHING CIRCUIT FOR CHILDREN BREATHING CIRCUIT FOR ADULTS	DD 1023663-1 NB 0197
CATHETER MOUNT with double swivel elbow connector, smooth-bore Basic UDI-DI: 59079968R020202-SMP	Class IIa	CATHETER MOUNT with double swivel elbow connector, smooth-bore	DD 1023663-1 NB 0197
CATHETER MOUNT with double swivel elbow connector, expandable	Class IIa	CATHETER MOUNT with double swivel	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: 59079968R020202-ELT		elbow connector, expandable	

CATHETER MOUNT with double swivel elbow connector, corrugated Basic UDI-DI: 59079968R020202-CLP	Class IIa	CATHETER MOUNT with double swivel elbow connector, corrugated	DD 1023663-1 NB 0197
CATHETER MOUNT with straight connector, smooth-bore Basic UDI-DI: 59079968R020201-SMJ	Class IIa	CATHETER MOUNT with straight connector, smooth-bore	DD 1023663-1 NB 0197
CATHETER MOUNT with straight connector, corrugated Basic UDI-DI: 59079968R020201-CLJ	Class IIa	CATHETER MOUNT with straight connector, corrugated	DD 1023663-1 NB 0197
CATHETER MOUNT with straight connector, expandable Basic UDI-DI: 59079968R020201-ELN	Class IIa	CATHETER MOUNT with straight connector, expandable	DD 1023663-1 NB 0197
CATHETER MOUNT with elbow connector, smooth-bore Basic UDI-DI: 59079968R0202-SHP	Class IIa	CATHETER MOUNT with elbow connector, smoothbore	DD 1023663-1 NB 0197
CATHETER MOUNT with elbow connector, corrugated Basic UDI-DI: 59079968R0202-CGP	Class IIa	CATHETER MOUNT with elbow connector, corrugated	DD 1023663-1 NB 0197
CATHETER MOUNT with elbow connector, expandable Basic UDI-DI: 59079968R0202-EGT	Class IIa	CATHETER MOUNT with elbow connector, expandable	DD 1023663-1 NB 0197
TRACHEOSTOMY TUBE cuffed Basic UDI-DI: 59079968R010502G4	Class IIa	TRACHEOSTOMY TUBE cuffed	DD 1023663-1 NB 0197
TRACHEOSTOMY TUBE uncuffed	Class IIa	TRACHEOSTOMY TUBE uncuffed	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: 59079968R010501G2			
LARYNGEAL MASK, PVC, disposable Basic UDI-DI: 59079968R0102-PH6	Class IIa	LARYNGEAL MASK, PVC, disposable	DD 1023663-1 NB 0197
LARYNGEAL MASK, silicone, disposable Basic UDI-DI: 59079968R0102-SHC	Class IIa	LARYNGEAL MASK, silicone, disposable	DD 1023663-1 NB 0197
AIR CUSHION ANAESTHETIC MASK Basic UDI-DI: 59079968R030101-CLQ	Class IIa	AIR CUSHION ANAESTHETIC MASK	DD 1023663-1 NB 0197
ANAESTHETIC MASK with open seal Basic UDI-DI: 59079968R030101-OMG	Class IIa	ANAESTHETIC MASK with open seal	DD 1023663-1 NB 0197
duoNEX Single use syringe, 2-part Basic UDI-DI: 59079968A0201020101DK	Class IIa	duoNEX Single use syringe, 2-part	DD 1023663-1 NB 0197
dicoNEX Single use syringe, 3-part (luer) Basic UDI-DI: 59079968A0201020102DM	Class IIa	dicoNEX Single use syringe, 3-part (luer)	DD 1023663-1 NB 0197
Apteczka ABC Strzykawka 3-częściowa Basic UDI-DI: 59079968A0201020102DM	Class IIa	Apteczka ABC Strzykawka 3częściowa	DD 1023663-1 NB 0197
dicoNEX Single use syringe, 3-part (luer lock) Basic UDI-DI: 59079968A0201020201DQ	Class IIa	dicoNEX Single use syringe, 3-part (luer lock)	DD 1023663-1 NB 0197

dicoNEX Single use amber syringe, 3-part (luer lock) 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)	Jeį 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

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

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
safeCARE Surgical gloves, latex, powdered Basic UDI-DI: 59079968T01010101-RYM	Class IIa	safeCARE Surgical gloves, latex, powdered	DD 1023663-1 NB 0197
safeCARE PF Surgical gloves powder free, sterile Basic UDI-DI: 59079968T01010102-RYS	Class IIa	safeCARE PF Surgical gloves powder free, sterile	DD 1023663-1 NB 0197
safeCARE basic Surgical gloves latex, powdered Basic UDI-DI: 59079968T01010101-RYM	Class IIa	safeCARE basic Surgical gloves latex, powdered	DD 1023663-1 NB 0197
safeCARE basic PF Surgical gloves latex, powder-free Basic UDI-DI: 59079968T01010102-RYS	Class IIa	safeCARE basic PF Surgical gloves latex, powder-free	DD 1023663-1 NB 0197

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 Basic UDI-DI: 59079968T010102-RYS	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
safeCARE synthetic Surgical gloves neoprene, powder-free safeCARE synthetic UG Surgical gloves neoprene, powder-free Basic UDI-DI: 59079968T010102-NRWL	Class IIa	safeCARE synthetic Surgical gloves neoprene, powder-free safeCARE synthetic UG Surgical gloves neoprene, powderfree	DD 1023663-1 NB 0197
safeCARE fusion Surgical gloves polyisoprene, powderfree	Class IIa	safeCARE fusion Surgical gloves polyisoprene, powder-free	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: 59079968T010102-PRWS			
safeCARE virtuo Surgical gloves flexylon, powderfree safeCARE virtuo UG Surgical gloves flexylon, powder-free safeCARE pro protect Surgical gloves flexylon, powder-free Basic UDI-DI: 59079968T010102-FRVU	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

safeLANCE Pressure-activated safety lancet	Class IIa	safeLANCE Pressure-activated safety lancet	DD 1023663-1 NB 0197
Basic UDI-DI: 59079968V0104RM			
deltaset Procedure kit O	Class IIa	deltaset Urinary bladder catheterization kit	DD 1023663-1 NB 0197
Basic UDI-DI: 59079968V0599-SETA			
deltaset Procedure kit O	Class IIa	deltaset Urinary bladder catheterization kit	DD 1023663-1 NB 0197
Basic UDI-DI: 59079968V0599-SHTG			
deltaset Procedure kit O	Class IIa	deltaset Dialysis kit	DD 1023663-1 NB 0197
Basic UDI-DI: 59079968V0599-CERS			
deltaset Procedure kit O	Class IIa	deltaset Dialysis kit	DD 1023663-1 NB 0197
Basic UDI-DI: 59079968V0599-CHRY			
deltaset Procedure kit O	Class IIa	deltaset Dressing change kit	DD 1023663-1 NB 0197
Basic UDI-DI: 59079968V0599-WETN			
deltaset Procedure kit O	Class IIa	deltaset Dressing change kit	DD 1023663-1 NB 0197
Basic UDI-DI: 59079968V0599-WHTU			
deltaset Procedure kit O	Class IIa	deltaset Suture application kit	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: 59079968V0599-RET7		deltaset Suture removal kit	

deltaset Procedure kit O Basic UDI-DI: 59079968V0599-RHTD	Class IIa	deltaset Suture application kit deltaset Suture removal kit	DD 1023663-1 NB 0197
deltaset Procedure kit O Basic UDI-DI: 59079968V0599-IESC	Class IIa	deltaset Anesthesia kit deltaset Puncture kit	DD 1023663-1 NB 0197
deltaset Procedure kit O Basic UDI-DI: 59079968V0599-IHSJ	Class IIa	deltaset Anesthesia kit deltaset Puncture kit	DD 1023663-1 NB 0197
elastopor STERIL Nonwoven dressing with absorbent pad, selfadhesive, sterile elastoKIDS STERIL Nonwoven dressing with absorbent pad, selfadhesive, sterile Basic UDI-DI: 59079968T0305RB	Class I devices placed on the market in sterile condition	elastopor STERIL Non-woven dressing with absorbent pad, self-adhesive, sterile elastoKIDS STERIL Nonwoven dressing with absorbent pad, self-adhesive, sterile	DD 1023663-1 NB 0197
elastoDERM PAD Foil dressing, with absorbent pad, selfadhesive, sterile Basic UDI-DI: 59079968M040101-FHU	Class I devices placed on the market in sterile condition	elastoDERM PAD Foil dressing, with absorbent pad, self-adhesive, sterile	DD 1023663-1 NB 0197
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	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
Basic UDI-DI: 59079968T0205R6			
ALPHAtex Procedure gown NORMAL-P Basic UDI-DI: 59079968T0205R6	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown NORMAL-P, sterile	HD 1023663-1 NB 0197
ALPHAtex Surgical gown STANDARD, sterile ALPHAtex Surgical gown COMFORT sterile Basic UDI-DI: 59079968T020401HA	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown STANDARD, sterile ALPHAtex Surgical gown COMFORT sterile	DD 1023663-1 NB 0197
ALPHAtex Surgical gown CLASSIC-P ALPHAtex Surgical gown STANDARD-P ALPHAtex Surgical gown COMFORT-P Basic UDI-DI: 59079968T020401HA	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown CLASSIC-P, sterile ALPHAtex Surgical gown STANDARD-P, sterile ALPHAtex Surgical gown COMFORT-P sterile	HD 1023663-1 NB 0197
ALPHAtex Surgical gown STANDARD PLUS, with impermeable parts, sterile ALPHAtex Surgical gown COMFORT PLUS, with impermeable parts, sterile ALPHAtex Surgical gown EXTRA SAFE, with impermeable parts, sterile Basic UDI-DI: 59079968T020402HC	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown STANDARD PLUS, with impermeable parts, sterile ALPHAtex Surgical gown COMFORT PLUS, with impermeable parts, sterile ALPHAtex Surgical gown EXTRA SAFE, with impermeable parts, sterile	DD 1023663-1 NB 0197

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	HD 1023663-1 NB 0197
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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
		impermeable parts, sterile	

ALPHAtex Surgical drape, sterile ALPHAtex 2-layer surgical drape, with cellulose layer, sterile ALPHAtex 2-layer surgical drape, sterile ALPHAtex 2-layer surgical drape with adhesive edge, sterile ALPHAtex 2-layer surgical drape with central fenestration, sterile ALPHAtex 2-layer surgical drape with central adhesive fenestration, sterile ALPHAtex 2-layer surgical drape with central, adjustable adhesive fenestration, sterile ALPHAtex 2-layer epidural surgical drape with adhesive fenestration, sterile ALPHAtex 3-layer surgical drape, sterile ALPHAtex 3-layer surgical drape with adhesive edge, sterile ALPHAtex 3-layer surgical drape with central fenestration, sterile ALPHAtex 3-layer surgical drape with central adhesive fenestration, sterile ALPHAtex Reinforced surgical drape with adhesive fenestration, sterile Basic UDI-DI: 59079968T0201QW	Class I devices placed on the market in sterile condition	ALPHAtex Surgical drape, sterile ALPHAtex 2-layer surgical drape, with cellulose layer, sterile ALPHAtex 2-layer surgical drape, sterile ALPHAtex 2-layer surgical drape with adhesive edge, sterile ALPHAtex 2-layer surgical drape with central fenestration, sterile ALPHAtex 2-layer surgical drape with central, adjustable adhesive fenestration, sterile ALPHAtex 2-layer epidural surgical drape with 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	DD 1023663-1 NB 0197
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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
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ALPHAtex Surgical drape ALPHAtex 2-layer surgical drape, with cellulose layer ALPHAtex 2-layer surgical drape ALPHAtex 2-layer surgical drape with adhesive edge ALPHAtex 2-layer surgical drape with central fenestration ALPHAtex 2-layer surgical drape with central adhesive fenestration ALPHAtex 3-layer surgical drape ALPHAtex 3-layer surgical drape with adhesive edge ALPHAtex 3-layer surgical drape with central fenestration ALPHAtex 3-layer surgical drape with central adhesive fenestration Basic UDI-DI: 59079968T0201QW	Class I devices placed on the market in sterile condition	ALPHAtex Surgical drape, sterile ALPHAtex 2-layer surgical drape, with cellulose layer, sterile ALPHAtex 2-layer surgical drape, sterile ALPHAtex 2-layer surgical drape with adhesive edge, sterile ALPHAtex 2-layer surgical drape with central fenestration, sterile ALPHAtex 2-layer epidural surgical drape with adhesive fenestration, sterile ALPHAtex 3-layer surgical drape, sterile ALPHAtex 3-layer surgical drape with adhesive edge, sterile ALPHAtex 3-layer surgical drape with central fenestration, sterile ALPHAtex 3-layer surgical drape with central adhesive fenestration, sterile	HD 1023663-1 NB 0197
ALPHAtex Instrument table cover, sterile Basic UDI-DI: 59079968T030101-INJ	Class I devices placed on the market in sterile condition	ALPHAtex Instrument table cover, sterile	DD 1023663-1 NB 0197
ALPHAtex Reinforced Mayo stand cover, sterile ALPHAtex Reinforced Mayo stand cover, red, sterile Basic UDI-DI: 59079968T030101-MNS	Class I devices placed on the market in sterile condition	ALPHAtex Reinforced Mayo stand cover, sterile ALPHAtex Reinforced Mayo stand cover, red, sterile	DD 1023663-1 NB 0197

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 Armboard cover, sterile ALPHAtex Surgical pocket for syringes, sterile Basic UDI-DI: 59079968T030101-NNU	Class I devices placed on the market in sterile condition	ALPHAtex Armboard cover, sterile ALPHAtex Surgical pocket for syringes, sterile	DD 1023663-1 NB 0197
ALPHAtex Camera cables cover, sterile ALPHAtex Circular banded cover for medical devices, sterile ALPHAtex Square banded cover for medical devices, sterile ALPHAtex C-arm cover set, sterile ALPHAtex Lamp handle cover, sterile ALPHAtex Ultrasound cover kits, sterile Basic UDI-DI: 59079968T030101-FNC	Class I devices placed on the market in sterile condition	ALPHAtex Camera cables cover, sterile ALPHAtex Circular banded cover for medical devices, sterile ALPHAtex Square banded cover for medical devices, sterile ALPHAtex C-arm cover set, sterile ALPHAtex Lamp handle cover, sterile ALPHAtex Ultrasound cover kits, sterile	DD 1023663-1 NB 0197
ALPHAtex Absorbent drape, sterile ALPHAtex Absorbent drape for newborn, sterile Basic UDI-DI: 59079968T020199-SRU	Class I devices placed on the market in sterile condition	ALPHAtex Absorbent drape, sterile ALPHAtex Absorbent drape for newborn, sterile	DD 1023663-1 NB 0197
ALPHAtex Absorbent drape, sterile ALPHAtex Absorbent drape for newborn, sterile Basic UDI-DI: 59079968T020199-SRU	Class I devices placed on the market in sterile condition	ALPHAtex Absorbent drape, sterile ALPHAtex Absorbent drape for newborn, sterile	HD 1023663-1 NB 0197
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	Class I devices placed on the	ALPHAtex Adhesive pouch,	DD 1023663-1 NB 0197
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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 Adhesive pouch, two-chamber, sterile ALPHAtex Arthroscopy fluid collection pouch, cone-shaped, with outlet tip, sterile ALPHAtex Fluid collection pouch, coneshaped, with outlet tip, sterile Basic UDI-DI: 59079968T020199-PRN	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	
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 Nonwoven surgical tape, adhesive, sterile ALPHAtex Velcro surgical tape, sterile	DD 1023663-1 NB 0197

ALPHAtex Abdominal drape, sterile ALPHAtex Abdo-Perineal drape, sterile ALPHAtex Angiography drape, sterile ALPHAtex Cardiology drape, sterile ALPHAtex Cardiac drape, sterile ALPHAtex C-section drape, sterile ALPHAtex Delivery drape, sterile ALPHAtex Extremity drape, sterile 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	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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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 Vertical isolation drape (from 1 to 100)	

ALPHAtex Abdominal set, sterile ALPHAtex Abdo-Perineal set, sterile ALPHAtex Ablation set, sterile ALPHAtex Angiography set, sterile ALPHAtex Arthroscopy set, sterile ALPHAtex Basic set, sterile ALPHAtex Cardiology set, sterile ALPHAtex Cardiac set, sterile ALPHAtex Craniotomy set, sterile ALPHAtex C-section set, sterile ALPHAtex Cystoscopy set, sterile ALPHAtex Delivery set, sterile ALPHAtex Dental set, sterile ALPHAtex Dynamic hip screw set, sterile ALPHAtex Extremity set, sterile ALPHAtex Gynaecology set, sterile ALPHAtex Hip set, sterile ALPHAtex Laparoscopy set, sterile 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	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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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
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ALPHAtex Thyroid set, sterile ALPHAtex TUR set, sterile ALPHAtex Universal set, sterile ALPHAtex Uro/gynaecology set, sterile ALPHAtex Varicose vein set, sterile ALPHAtex Vertical isolation set, sterile Basic UDI-DI: 59079968T0202QY		ALPHAtex Ophthalmic set, sterile ALPHAtex Otolaryngology set, sterile ALPHAtex Pediatric set, sterile ALPHAtex Percutaneous lithotripsy set, sterile ALPHAtex Shoulder set, sterile ALPHAtex Spine set, sterile ALPHAtex Thyroid set, sterile ALPHAtex TUR set, sterile ALPHAtex Universal set, sterile ALPHAtex Uro/gynaecology set, sterile ALPHAtex Varicose vein set, sterile ALPHAtex Vertical isolation set, sterile	
ALPHAtex Abdominal set, sterile ALPHAtex Abdo-Perineal set, sterile ALPHAtex Ablation set, sterile 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	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)"	
elastoLUMENAL S Eye pad, superabsorbent, multi-layer, sterile Basic UDI-DI: 59079968M040301-SKC	Class I devices placed on the market in sterile condition	elastoLUMENAL S Eye pad, superabsorbent, multi-layer, sterile	DD 1023663-1 NB 0197
elastopor EYE Eye dressing, non-woven, with absorbent pad, selfadhesive, sterile elastoKIDS EYE Eye dressing, non-woven, with absorbent pad, selfadhesive, sterile Basic UDI-DI: 59079968M0403NX	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
COMBI STOPPER Basic UDI-DI: 59079968C01018085	Class I devices placed on the market in sterile condition	COMBI STOPPER	DD 1023663-1 NB 0197
LUER LOCK STOPPER Basic UDI-DI: 59079968C01018085	Class I devices placed on the market in sterile condition	LUER LOCK STOPPER	DD 1023663-1 NB 0197

elastopor STERIL D Nonwoven dressing with absorbent pad, with incision and O-hole, selfadhesive, sterile elastoKIDS STERIL D Non-woven dressing, with absorbent pad, with	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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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
incision and X-hole, selfadhesive, sterile Basic UDI-DI: 59079968M04010201-DTG		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	
NONVI lux S Non-woven swab, with O-incision, sterile NONVI lux S Non-woven swab, with Y-incision, sterile Basic UDI-DI: 59079968M04010201-NU4	Class I devices placed on the market in sterile condition	NONVI lux S Nonwoven swab, with O-incision, sterile NONVI lux S Nonwoven swab, with Y-incision, sterile	DD 1023663-1 NB 0197
elastopor IV IV cannula dressing, non-woven, selfadhesive, sterile elastoKIDS IV IV cannula dressing, non-woven, selfadhesive, sterile Basic UDI-DI: 59079968M04010201H2	Class I devices placed on the market in sterile condition	elastopor IV IV cannula dressing, non-woven, selfadhesive, sterile elastoKIDS IV IV cannula dressing, non- woven, selfadhesive, sterile	DD 1023663-1 NB 0197

elastoDERM F-IV IV cannula dressing, foil, with frame, with 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 Basic UDI-DI: 59079968M04010202H4	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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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
MULTIabsorb S ABD pad, non-woven and cellulose, sterile Basic UDI-DI: 59079968M040201-SJZ	Class I devices placed on the market in sterile condition	MULTIabsorb S ABD pad, nonwoven and cellulose, sterile	DD 1023663-1 NB 0197
VAGINAL SPECULUM Basic UDI-DI: 59079968U089006MJ	Class I devices placed on the market in sterile condition	VAGINAL SPECULUM	DD 1023663-1 NB 0197
URINE BAG Basic UDI-DI: 59079968A0603038J	Class I devices placed on the market in sterile condition	URINE BAG	DD 1023663-1 NB 0197
URINE BAG with sample port, sterile URINE BAG with sample port 2W, sterile Basic UDI-DI: 59079968A060303-PBW	Class I devices placed on the market in sterile condition	URINE BAG with sample port, sterile URINE BAG with sample port 2W, sterile	DD 1023663-1 NB 0197

SAMPLES TAKING URINE BAG for boys, with sponge SAMPLES TAKING URINE BAG for boys, without sponge SAMPLES TAKING URINE BAG for girls, with sponge SAMPLES TAKING URINE BAG for girls, without sponge Apteczka ABC Woreczek do pobierania próbek moczu dla dla chłopców z gąbką Apteczka ABC Woreczek do pobierania próbek moczu dla dziewczynek z gąbką Basic UDI-DI: 59079968A06030301AB	Class I devices placed on the market in sterile condition	SAMPLES TAKING URINE BAG for boys, with sponge SAMPLES TAKING URINE BAG for boys, without sponge SAMPLES TAKING URINE BAG for girls, with sponge SAMPLES TAKING URINE BAG for girls, without sponge Apteczka ABC Woreczek do pobierania próbek moczu dla dla chłopców z gąbką Apteczka ABC Woreczek do pobierania próbek moczu dla dziewczynek z gabka	DD 1023663-1 NB 0197
ENEMA BAG sterile Basic UDI-DI: 59079968G020301-SDY	Class I devices placed on the market in sterile condition	ENEMA BAG sterile	DD 1023663-1 NB 0197

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
WOODEN TONGUE DEPRESSOR Sterile Basic UDI-DI: 59079968V9001-SNM	Class I devices placed on the market in sterile condition	WOODEN TONGUE DEPRESSOR sterile	DD 1023663-1 NB 0197
NELATON CATHETER NELATON CATHETER transparent Basic UDI-DI: 59079968U010105H9	Class I devices placed on the market in sterile condition	NELATON CATHETER NELATON CATHETER transparent	DD 1023663-1 NB 0197
GUEDEL AIRWAY Basic UDI-DI: 59079968R010102FG	Class I devices placed on the market in sterile condition	GUEDEL AIRWAY	DD 1023663-1 NB 0197

ENDOTRACHEAL TUBE HOLDER, vertical fixation ENDOTRACHEAL TUBE HOLDER, horizontal fixation Basic UDI-DI: 59079968R010380-SNX	Class I devices placed on the market in sterile condition	ENDOTRACHEAL TUBE HOLDER, vertical fixation ENDOTRACHEAL TUBE HOLDER, horizontal fixation	DD 1023663-1 NB 0197
INTUBATION STYLET TRACHEAL TUBE INTRODUCER CURVED Basic UDI-DI: 59079968R010380-PNR	Class I devices placed on the market in sterile condition	INTUBATION STYLET TRACHEAL TUBE INTRODUCER CURVED	DD 1023663-1 NB 0197
dicoSPIKE Withdrawal cannula with bacteria filter dicoSPIKE Withdrawal cannula with bacteria and particle filter dicoSPIKE Chemo Withdrawal cannula with bacteria and particle filter Basic UDI-DI: 59079968A0704KC	Class I devices placed on the market in sterile condition	dicoSPIKE Withdrawal cannula with bacteria filter dicoSPIKE Withdrawal cannula with bacteria and particle filter dicoSPIKE Chemo Withdrawal cannula with bacteria and particle filter	DD 1023663-1 NB 0197
elastoBAND BASIC S Knitted supporting bandage, sterile Basic UDI-DI: 59079968M030301-SJT	Class I devices placed on the market in sterile condition	elastoBAND BASIC S Knitted supporting bandage, sterile	HD 1023663-1 NB 0197
elastoBAND FLEX S Elastic bandage, sterile	Class I devices placed on the	elastoBAND FLEX S	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: 59079968M030402-SKB	market in sterile condition	Elastic bandage, sterile	

elastoFILM Incise film, self-adhesive, sterile elastoFILM M Incise film, self-adhesive, sterile Basic UDI-DI: 59079968T020101GT	Class I devices placed on the market in sterile condition	elastoFILM Incise film, self-adhesive, sterile elastoFILM M Incise film, selfadhesive, sterile	DD 1023663-1 NB 0197
CERVICAL BRUSH standard CERVICAL BRUSH special Basic UDI-DI: 59079968U090303L7	Class I devices placed on the market in sterile condition	CERVICAL BRUSH standard CERVICAL BRUSH special	DD 1023663-1 NB 0197
omegapack Surgical set B Basic UDI-DI: 59079968V0599-EP2	Class IIb excluding Class IIb implantable non-WET	omegapack Surgical set B Orthopedic surgery set B Universal set B Surgical set B Orthopedic surgery set B Universal set B	HD 1023663-1 NB 0197
omegapack Surgical set B Basic UDI-DI: 59079968V0599-KPE	Class IIb excluding Class IIb implantable non-WET	omegapack Surgical set B Orthopedic surgery set B Universal set B Surgical set B Orthopedic surgery set B Universal set B	HD 1023663-1 NB 0197
omegapack Surgical set Basic UDI-DI: 59079968V0599-ANS	Class IIa	omegapack Surgical set Angiography set C-section set Laparoscopy set Gynecological surgery set Cardiac surgery set Neurosurgical set Orthopedic surgery set Otolaryngologic surgery set Urologic surgery set Delivery set Dressing set	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

deltaset Procedure kit Basic UDI-DI: 59079968V0599-UITQ	Class I devices placed on the market in sterile condition	deltaset Universal kit I	HD 1023663-1 NB 0197
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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
deltaset Procedure kit Basic UDI-DI: 59079968V0599-BIRX	Class I devices placed on the market in sterile condition	deltaset Dialysis kit	HD 1023663-1 NB 0197
deltaset Procedure kit Basic UDI-DI: 59079968V0599-MISY	Class I devices placed on the market in sterile condition	deltaset Universal kit I	HD 1023663-1 NB 0197
deltaset Procedure kit Basic UDI-DI: 59079968V0599-DIS5	Class I devices placed on the market in sterile condition	deltaset Operating field disinfection kit I	HD 1023663-1 NB 0197
deltaset Procedure kit Basic UDI-DI: 59079968V0599-ZIU7	Class I devices placed on the market in sterile condition	deltaset Suture removal kit I	HD 1023663-1 NB 0197
deltaset Procedure kit Basic UDI-DI: 59079968V0599-PIT9	Class I devices placed on the market in sterile condition	deltaset Protective kit I Hygiene kit I Neonatal kit I	HD 1023663-1 NB 0197

2 lentelė. Prietaisai, kuriems taikomas šis raštas ir už kuriuos NB NĖRA atsakinga už tinkamą 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
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