

EU Atitikties deklaracija

Radiometer Medical ApS Åkandevej 21 2700 Brønshøj Danija	SRN: DK-MF-000016271
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Mes, "Radiometer Medical ApS", išleisdami šį DoC pareiškiame, kad mes, kaip gamintojas, prisiimame visą atsakomybę už toliau išvardytus gaminius.

Mes, Radiometer Medical ApS, pareiškiame, kad toliau nurodytas (-i) gaminys (-iai) atitinka taikomus 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/46 dėl in vitro diagnostikos medicinos prietaisų reikalavimus, kaip nurodyta IV priede.

Rizikos klasifikavimas pagal VIII priedą

Class A

Produktų grupė:

Name	Ref No.	Basic UDI-DI	EMDN	GMDN
safeCLINITUBES D941P-NA-240-55x3	942-889	57006900069ND	W0501010203	61387
safeCLINITUBES D941P-240-85x1	942-890	57006900069ND	W0501010203	61387
safeCLINITUBES D941P-NA-240-85x3	942-891	57006900069ND	W0501010203	61387
safeCLINITUBES D957P-70-100x1	942-892	57006900069ND	W0501010203	61419
safeCLINITUBES D957P-70-125x1	942-893	57006900069ND	W0501010203	61419
safeCLINITUBES D957P-70-70x1	942-898	57006900069ND	W0501010203	61419
safeCLINITUBES D957P-70-45x1	942-969	57006900069ND	W0501010203	61419
Intended purpose Heparinized capillary tubes intended for blood sampling				

Name	Ref No.	Basic UDI-DI	EMDN	GMDN
Capillary caps x 500	905-787	57006900098NL	W0501010280	66068
Intended purpose Caps to seal a capillary tube sample				

Name	Ref No.	Basic UDI-DI	EMDN	GMDN
Mixing wires	905-788	57006900099NN	W0501010280	65601
Intended purpose Mixing wire to be placed into the capillary tube to mix the sample				

Name	Ref No.	Basic UDI-DI	EMDN	GMDN
Magnet for CLINITUBES	912-065	57006900100ME	W0501010280	66396
Intended purpose Mixing magnet to facilitate movement of the mixing wire in a capillary tube sample				

Bendra specifikacija

Šiuo metu netaikoma

Pirmos atitikties deklaracijos data: 2022-09-27

Išleidimas:

<u>Trine Østerby</u> signature	<u>Copenhagen, Denmark</u> Issued in	<u>07-Oct-2022</u> Date
<u>Trine Østerby</u> Name	<u>Director, RA</u> Position	