

EU Declaration of Conformity

Radiometer Medical ApS Åkandevej 21 2700 Brønshøj Denmark	SRN: DK-MF-000016271
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We, Radiometer Medical ApS, declare with the issue of this DoC, that we as manufacturer take the sole responsibility for the products mentioned below.

We, Radiometer Medical ApS, declare that the below mentioned product(s) meet(s) the applicable requirements of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic Medical Devices, as specified in annex IV.

RISK Classification in accordance with Annex VIII:

Class A

Product family: Capillary tubes

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				

Common Specification:

Currently non-applicable

Date of the first issuance of the EU Declaration of Conformity: 2022-09-27

Issuance:

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

1 Change History

Revision	Author	Change Description
001	JOHAH	Document established
002	JOHAH	Revised product name for Ref Nos 942-889 and 942-891