EU Declaration of Conformity

Radiometer Medical ApS Åkandevej 21 2700 Brønshøj Denmark	**SRN:** DK-MF-000016271

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: *ABL accessories*

Name	Ref No.	Basic UDI-DI	EMDN	GMDN
Hypochlorite Solution (S5362)	943-906	57006900090N4	W0201040185	59058
Intended purpose				
Intended for protein removal and decontamination of ABL analyzers.				

Common Specification:

Currently non-applicable

Date of the first issuance of the EU Declaration of Conformity: *2022-11-23*

Issuance:

Signature	Issued in	Date
	Copenhagen, Denmark	2022-11-23

Name	Position
Noopur Gupta	Director, Regulatory Affairs

1 Change History

Revision	Author	Change Description
001	LINST	Document established