RADIOMETER

EC Declaration of Conformity

Radiometer Medical ApS

Åkandevej 21

DK-2700 Brønshøj

Denmark

We hereby declare that the product(s) described below meets the applicable requirements of Directive 98/79/EC of the European Parliament and of the Council of October 27, 1998, on *in vitro* diagnostic medical devices (IVDD) as specified in Annex III.

Class: ☒ General ☐ Annex II/List A ☐ Annex II/List B

Product family: ABL800 FLEX blood gas, oximetry, electrolyte, and metabolite analyzer

Name	Ref. No.	GMDN	CE-mark
ABL800 BASIC w/Autocheck	393-844	56676	2007-01
ABL800 FLEX w/Autocheck	393-845	56676	2006-09
ABL805 w/Autocheck & FLEXQ	393-805	56676	2007-01
ABL805 w/Autocheck	393-806	56676	2005-01
ABL810, ABL820, ABL830 w/Autocheck & FLEXQ	393-820	56676	2005-12
ABL810, ABL820, ABL830 w/Autocheck	393-821	56676	2005-12
ABL815, ABL825, ABL835 w/Autocheck & FLEXQ	393-825	56676	2006-02
ABL815, ABL825, ABL835 w/Autocheck	393-826	56676	2004-09

Issuance:

Name: Anna Jessen Place: Copenhagen, Denmark

Title: Sr.Director Regulatory Affairs

Signature: Date: 29 Mar 2021

1 Change History

Revision	Author	Change Description
01	ZAL	New form is applied. Item number 393-803 and 393-804 are discontinued.
02	ZAL	GMDN code has been corrected from 56669 to 56667
03	ZAL	GMDN code has been corrected from 56667 to 56676