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
☐ Self-testing ☐ Performance Evaluation

Product family: ABL800 FLEX blood gas analyzer, Software version 5.21 or higher

Model Name	Article No.	Ref. No.	GMDN Code*	From Serial/ LOT No.
ABL805 w/Autocheck	N/A	393-806	30847	N/A
ABL810 BG only w/Autocheck	N/A	393-804	30847	N/A
ABL810, ABL820, ABL830 w/Autocheck	N/A	393-821	30847	N/A
ABL815, ABL825, ABL835 w/Autocheck	N/A	393-826	30847	N/A
ABL800 FLEX w/Autocheck	N/A	393-845	30847	N/A

*: According to the nomenclature provided in ISO/TS-20225

Notified Body:

As specified in the Directive and Annex mentioned above, the conformity assessment procedure for this class of product does not require the involvement of a Notified Body.

Issuance:

Name: Jana S. Hellmann
Title: VP RA/QA

Place: Copenhagen, Denmark

Signature: 

Date: 2009-08-06