RADIOMETER COPENHAGEN

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: ABL 8xx analyzers

Model Name	Article No.	Ref. No.	GMDN Code*	From Serial/ LOT No.
Cleaning Solution with additive	S8375	944-126	30210	WJ-01 and onwards

*: 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: Eva G. Henriksen
Title: RA Manager
Signature:

Place: Copenhagen, Denmark
Date: 2008-12-04