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: ABL90 FLEX Series, from Software version V2.3

Name	Ref. No.	GMDN	CE-mark
ABL90 FLEX Analyzer	393-090	56667	2009-12
ABL90 FLEX PLUS Analyzer	393-092	56667	2015-02
ABL90 FLEX Flush Device	905-918	56667	2012-02
ABL90 FLEX sBox	905-917	56667	2012-02
ABL90 FLEX sBox PLUS	905-956	56667	2015-02
Clot Catcher	906-026	56667	2010-06
QUALICHECK Opener/Adapter	925-214	56667	2017-05
ABL90 FLEX Inlet Clip	925-047	56667	2011-10

Name	Ref. No.	GMDN	CE-mark
ABL90 FLEX Sensor Cassette			
Sensor Cassette Pack (SC90)	946-005	52858	2009-12
Sensor Cassette Pack (SC90)	946-008	52858	2010-05
Sensor Cassette Pack (SC90)	946-009	52858	2010-10
Sensor Cassette Pack (SC90)	946-010	52858	2012-05
Sensor Cassette Pack (SC90)	946-013	52858	2010-08
Sensor Cassette Pack (SC90)	946-059	52858	2012-11
Sensor Cassette Pack (SC90)	946-060	52858	2015-10
Sensor Cassette Pack (SC90)	946-061	52858	2017-01
Sensor Cassette Pack (SC90)	946-062	52858	2017-01
Sensor Cassette Pack (SC90)	946-063	52858	2017-01
Sensor Cassette Pack (SC90 Ki)	946-705	52858	2017-05
ABL90 FLEX Solution Pack			
Solution Pack – SP90	944-157	52858	2009-12
Solution Pack – SP90	944-197	52858	2009-12
Solution Pack – SP90	944-457	52858	2015-01
Solution Pack – SP90	944-497	52858	2015-01
Solution Pack – SP90 Ki	944-369	52858	2017-05
Solution Pack – SP90 Ki	944-370	52858	2017-05

Issuance:

Name: Place: Copenhagen, Denmark

Title: Senior Director Regulatory Affairs

Signature: Date: 2017-11-30

1 Change History

Revision	Author	Change Description
1	ZAL	New Form FRM-02230 is implemented Item number 924-646 is discont inued