

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 – Solutions and Accessories

Name	Ref. No.	GMDN	CE-mark
S8375 Cleaning solution with additive	944-126	59058	2008-12
S1820 Calibration solution 1	944-127	35933	2004-12
S1820 Calibration solution 1	944-128	35933	2004-12
S1830 Calibration solution 2	944-129	35933	2004-12
S4980 Rinse solution	944-130	59058	2004-12
S4980 Rinse solution	944-131	59058	2004-12
S4980 Rinse solution	944-132	59058	2004-12
S1827 Calibration Solution 1	944-133	35933	2006-11
S1837 Calibration Solution 2	944-134	35933	2006-11
S1827 Calibration Solution 1	944-135	35933	2006-11
S8377 Cleaning Met II Solution	944-136	59058	2006-11
S4987 Rinse solution II	944-155	59058	2006-11
S4987 Rinse solution II	944-158	59058	2006-11
S4987 Rinse solution II	944-159	59058	2006-11

Issuance:

Name: Gitte Juel Friis

Place: Copenhagen, Denmark

Title: Director Regulatory Affairs

Signature:

Date: 2018-01-08

1 Change History

Revision	Author	Change Description
01	ZAL	Item no. 944-127,944-130,944-131,944-135,944-155,944-158 are added. Products are outside EU item number similar to EU item numbers.