

EC Declaration of Conformity

Radiometer Medical ApS

Åkandevvej 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: ABL80FLEX with Software v1.00 or higher and ABL80FLEX with Basic Software Configuration, Software v1.40 or higher.

Model Name	Article No.	Ref. No.	GMDN Code*	From Serial/ LOT No/Run.
ABL 80FLEX Analyzer	N/A	393-839	30847	Serial nr: 300101
Capillary Adapters	N/A	906-022	37565	
Fluidics kit	N/A	905-674	31336	
ABL80FLEX Sensor Cassettes				Lot nr:
SC80 Sensor Cassettes	N/A	945-665	30201	13953
SC80 Sensor Cassettes	N/A	945-666	30201	13953
SC80 Sensor Cassettes	N/A	945-667	30201	13953
SC80 Sensor Cassettes	N/A	945-668	30201	13953
SC80 Sensor Cassettes	N/A	945-669	30201	13953
SC80 Sensor Cassettes	N/A	945-670	30201	13953
SC80 Sensor Cassettes	N/A	945-671	30201	13953
SC80 Sensor Cassettes	N/A	945-672	30201	13953
SC80 Sensor Cassettes	N/A	945-673	30201	13953
SC80 Sensor Cassettes	N/A	945-674	30201	13953
SC80 Sensor Cassettes	N/A	945-675	30201	13953
SC80 Sensor Cassettes	N/A	945-676	30201	13953
SC80 Sensor Cassettes	N/A	945-677	30201	13953
SC80 Sensor Cassettes	N/A	945-678	30201	13953
SC80 Sensor Cassettes	N/A	945-679	30201	13953
SC80 Sensor Cassettes	N/A	945-680	30201	13953
SC80 Sensor Cassettes	N/A	945-681	30201	13953
SC80 Sensor Cassettes	N/A	945-682	30201	13953
SC80 Sensor Cassettes	N/A	945-683	30201	13953
SC80 Sensor Cassettes	N/A	945-684	30201	13953

SC80 Sensor Cassettes	N/A	945-685	30201	13953
SC80 Sensor Cassettes	N/A	945-686	30201	13953
SC80 Sensor Cassettes	N/A	945-687	30201	13953
SC80 Sensor Cassettes	N/A	945-688	30201	13953
SC80 Sensor Cassettes	N/A	945-689	30201	13953
SC80 Sensor Cassettes	N/A	945-690	30201	13953
SC80 Sensor Cassettes	N/A	945-691	30201	13953
SC80 Sensor Cassettes	N/A	945-692	30201	13953
SC80 Sensor Cassettes	N/A	945-693	30201	13953
SC80 Sensor Cassettes	N/A	945-694	30201	13953
SC80 Sensor Cassettes	N/A	945-768	30201	13953
SC80 Sensor Cassettes	N/A	945-769	30201	13953
SC80 Sensor Cassettes	N/A	945-770	30201	13953
SC80 Sensor Cassettes	N/A	945-771	30201	13953
SC80 Sensor Cassettes	N/A	945-772	30201	13953
SC80 Sensor Cassettes	N/A	945-773	30201	13953
BASIC Sensor Cassettes				
SC80 Sensor Cassettes	N/A	945-774	30201	42802
SC80 Sensor Cassettes	N/A	945-775	30201	42802
SC80 Sensor Cassettes	N/A	945-776	30201	42802
SC80 Sensor Cassettes	N/A	945-777	30201	42802
SC80 Sensor Cassettes	N/A	945-778	30201	42802
SC80 Sensor Cassettes	N/A	945-779	30201	42802
SC80 Sensor Cassettes	N/A	945-780	30201	42802
SC80 Sensor Cassettes	N/A	945-783	30201	42802
SC80 Sensor Cassettes	N/A	945-784	30201	42802
SC80 Sensor Cassettes	N/A	945-785	30201	42802
SC80 Sensor Cassettes	N/A	945-786	30201	42802
SC80 Sensor Cassettes	N/A	945-787	30201	42802
SC80 Sensor Cassettes	N/A	945-788	30201	42802
SC80 Sensor Cassettes	N/A	945-789	30201	42802
SC80 Sensor Cassettes	N/A	945-790	30201	42802
SC80 Sensor Cassettes	N/A	945-793	30201	42802
ABL80FLEX Solution Pack				
ABL 80 Solution Pack	N/A	944-174	35933	14154
BASIC Solution Pack				
ABL80 Solution Pack	N/A	944-309	35933	44116
ABL80FLEX Cleaning Pack				
Cleaning Pack for ABL80FLEX	N/A	920-753	30210	41522
ABL80FLEX Sensor Cassette for use with Cleaning Pack.	N/A	920-755	30201	41727
ABL80FLEX Basic Software Configuration				
BASIC SW	N/A	933-081	N/A	N/A
BASIC Option key	N/A	933-085	N/A	N/A
FLEX SW	N/A	933-082	N/A	N/A
FLEX Option key	N/A	933-087	N/A	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: Lone Rønnemoes Pedersen
Title: Regulatory Affairs Manager

Place: Copenhagen, Denmark

Signature: 

Date: 2010-01-27

