

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: AutoCheck

Name	Ref. No.	GMDN	CE-mark
S7335 AutoCheck3+ LEVEL 1	944-082	52860	2003-12
S7345 AutoCheck3+ LEVEL 2	944-083	52860	2004-02
S7355 AutoCheck3+ LEVEL 3	944-084	52860	2004-02
S7365 AutoCheck3+ LEVEL 4	944-085	52860	2003-12
S7735 AutoCheck5+ LEVEL 1	944-074	52860	2003-12
S7745 AutoCheck5+ LEVEL 2	944-075	52860	2003-12
S7755 AutoCheck5+ LEVEL 3	944-076	52860	2003-12
S7765 AutoCheck5+ LEVEL 4	944-077	52860	2003-12
S7835 AutoCheck6+ LEVEL 1	944-094	52860	2006-11
S7845 AutoCheck6+ LEVEL 2	944-095	52860	2006-11
S7855 AutoCheck6+ LEVEL 3	944-096	52860	2006-11
S7865 AutoCheck6+ LEVEL 4	944-097	52860	2006-11

Issuance:

Name: Gitte Juel Friis

Place: Copenhagen, Denmark

Title: Sr. Director Regulatory Affairs

Signature: 

Date: 2019-10-15

1 Change History

Revision	Author	Change Description
01	ZAL	New form is implemented