

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: AQT90 FLEX series

Name	Ref. No.	GMDN	CE-mark
AQT90 FLEX Analyzer	393-838	56705	2008-01
AQT90 FLEX Solution Pack	903-006	58236	2008-01
Cleaning Tube Solution	905-843	38773	2012-11
Hct upgrade kit for AQT90 FLEX	905-902	56705	2011-10
Empty Tube Kit	944-230	46327	2011-10
Blank Cartridge	942-962	46327	2011-10
TnI Test kit	942-903	53996	2008-01
TnI CAL Cartridge	944-212	53999	2009-05
CKMB Test kit	942-906	61385	2008-03
CKMB CAL Cartridge	944-216	44694	2009-05
Myo Test kit	942-909	61390	2008-03
Myo CAL Cartridge	944-214	41733	2009-05
D-dimer Test kit	942-915	61389	2009-04
D-dimer CAL Cartridge	944-220	47348	2009-04
βhCG Test kit	942-918	58789	2008-11
βhCG CAL Cartridge	944-222	42730	2008-11
NT-proBNP Test kit	942-930	47352	2008-12
NT-proBNP CAL Cartridge	944-258	47353	2008-12
CRP Test kit	942-936	58768	2008-12
CRP CAL Cartridge	944-267	41838	2008-12
TnT Test kit	942-940	53996	2010-06
TnT (8 test) Test kit	942-967	53996	2014-10
TnT CAL Cartridge	944-268	53996	2010-06
PCT Test Kit	942-964	54313	2015-03
PCT (8-test) Test Kit	942-970	54313	2015-03
PCT CAL Cartridge	944-394	54314	2015-03

Name	Ref. No.	GMDN	CE-mark
LQC Multi-CHECK level 1	944-231	47016	2008-12
LQC Multi-CHECK level 2	944-232	47016	2008-12
LQC Multi-CHECK level 3	944-233	47016	2008-12
LQC D-dimer-CHECK level 1	944-234	47347	2009-08
LQC D-dimer-CHECK level 2	944-235	47347	2009-08
LQC hCG-CHECK level 1	944-236	42729	2009-08
LQC hCG-CHECK level 2	944-237	42749	2009-08
LQC CRP-CHECK level 1	944-299	41839	2011-03
LQC CRP-CHECK level 2	944-300	41839	2011-03
LQC TnT-CHECK level 1	944-371	54000	2012-01
LQC TnT-CHECK level 2	944-372	54000	2012-01
LQC TnT-CHECK level 3	944-373	54000	2012-01
LQC PCT-CHECK level 1	944-410	54315	2015-03
LQC PCT-CHECK level 2	944-411	54315	2015-03

Issuance:

Name: Gitte Juel Friis
Title: Director Regulatory Affairs

Place: Copenhagen, Denmark

Signature:

Gitte Juel Friis

Date:

2015-03-18