EU Declaration of Conformity

Radiometer Medical A/S
Åkandevej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

D999 Membrane box for E909 electrode – pO_2

REF 942-042 from LOT 766 and onward

complies with the provisions in the directive:

98/79/EC (IVDD) Annex III

Issued (place): Copenhagen

Date: December 5, 2003 by: Kirsten Rønø

Director of Quality

Signature:

F1544, Rev. 2, IS 62-00-001

RADIOMETER COPENHAGEN

Digitally signed by Iurchevici Valeriu
Date: 2019.07.25 16:50:22 EEST
Reason: MoldSign Signature
Location: Moldova

EU Declaration of Conformity

Radiometer Medical A/S
Åkandevej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

D888 Membrane box for E808 electrode – pCO_2

REF 942-043 from LOT 740 and onward

complies with the provisions in the directive:

98/79/EC (IVDD) Annex III

Issued (place): Copenhagen

Date: December 4, 2003 by: Kirsten Rønø

Director of Quality

Signature:

F1544, Rev. 2, IS 62-00-001

RADIOMETER COPENHAGEN

EU Declaration of Conformity

Radiometer Medical A/S
Åkandevej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

S5362 Hypochlorite Solution

REF 943-906 from LOT NE-01 and onward

complies with the provisions in the directive:

98/79/EC (IVDD) Annex III

Issued (place): Copenhagen

Date: December 4, 2003 by: Kirsten Rønø

Director of Quality

Signature:

RADIOMETER COPENHAGEN

EU Declaration of Conformity

Radiometer Medical A/S
Åkandevej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

S5384 Cleaning Solution

REF 944-028 from LOT NJ-01 and onward

complies with the provisions in the directive:

98/79/EC (IVDD) Annex III

Issued (place): Copenhagen

Date: February 3, 2004 by: Kirsten Rønø

Director of Quality

Signature:

F1544, Rev. 2, IS 62-00-001

RADIOMETER COPENHAGEN

EU Declaration of Conformity

Radiometer Medical A/S
Åkandevej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

S4944 Salt-Bridge Solution

REF 944-029 from LOT NJ-01 and onward

complies with the provisions in the directive:

98/79/EC (IVDD) Annex III

Issued (place): Copenhagen

Date: December 4, 2003 by: Kirsten Rønø

Director of Quality

Signature:

RADIOMETER COPENHAGEN

EU Declaration of Conformity

Radiometer Medical A/S
Åkandevej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

S1584 Calibrating Solution 1

REF 944-030 from LOT 13 and onward

complies with the provisions in the directive:

98/79/EC (IVDD) Annex III

Issued (place): Copenhagen

Date: December 4, 2003 by: Kirsten Rønø

Director of Quality

Signature:

RADIOMETER COPENHAGEN

EU Declaration of Conformity

Radiometer Medical A/S
Åkandevej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

S1594 Calibrating Solution 2

REF 944-031 from LOT NR-01 and onward

complies with the provisions in the directive:

98/79/EC (IVDD) Annex III

Issued (place): Copenhagen

Date: December 5, 2003 by: Kirsten Rønø

Director of Quality

Signature:

RADIOMETER COPENHAGEN

EU Declaration of Conformity

Radiometer Medical A/S
Åkandevej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

S4934 Rinse Solution

REF 944-032 from LOT NE-01 and onward

complies with the provisions in the directive:

98/79/EC (IVDD) Annex III

Issued (place): Copenhagen

Date: December 4, 2003 by: Kirsten Rønø

Director of Quality

Signature:

RADIOMETER COPENHAGEN

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
☐ Self-testing ☐ Performance Evaluation

Product family:

Model Name	Article No.	Ref. No.	GMDN Code*	From Serial/ LOT No.
QUALICHECK4+ Level 2	S7440	944-054	30218	017

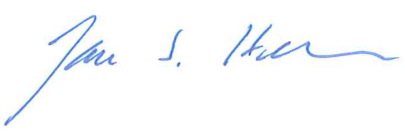
*: According to the nomenclature provided in ISO/TS-20225

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: Jana S. Hellmann
Title: Regulatory Affairs Manager
Place: Copenhagen, Denmark

Signature: 
Date: 2011-09-29

EU Declaration of Conformity

Radiometer Medical A/S
Åkandevej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

E808 Electrode for ABL analyzers – pCO_2

REF 945-375 from LOT NE-01 and onward

complies with the provisions in the directive:

98/79/EC (IVDD) Annex III

Issued (place): Copenhagen

Date: December 4, 2003 by: Kirsten Rønø

Director of Quality

Signature:

RADIOMETER COPENHAGEN

EU Declaration of Conformity

Radiometer Medical A/S
Åkandevej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

Tube for sample aspiration

REF 956-381

delivered from Radiometer Medical A/S after 2003-12-07, complies with the provisions in the directive:

98/79/EC (IVDD) Annex III

Issued (place): Copenhagen

Date: December 11, 2003 by: Kirsten Rønø

Director of Quality

Signature:

RADIOMETER COPENHAGEN