

To whom it may concern

Radiometer Medical ApS
Åkandevej 21
2700 Brønshøj
Denmark
Phone: +45 38 27 38 27
Fax: +45 38 27 27 27
CVR No. 27 50 91 85
www.radiometer.com

April 15, 2010

AUTHORIZATION

Hereby we, company Radiometer Medical ApS, Aakandevej 21, DK-2700 Bronshøj, Denmark, authorize Echipamed Plus, Valea Trandafirilor str. 24B, off. 80, MD-2001 Chisinau, Moldova, to be our official and exclusive distributor on the territory of Moldova, at its own expense and peril to participate in negotiations, tenders, to sign contracts and to execute any other actions necessary for sale and marketing of our products in Moldova.

This authorization is valid till revoked.

Kind regards
Radiometer Medical ApS



International Sales Division
Åkandevvej 21
DK-2700 · Brønshøj · Denmark
Phone: +45 38 27 38 27
Phone (dir.): +45 38 27 21 64
Fax: +45 38 27 27 11
CVR No.: 13496188
e-mail: rint@rint.dk
<http://www.radiometer.com>

Declaration about secure use of Radiometer equipment

Best regards
RADIOMETER MEDICAL ApS
International Sales Division



To whom it may concern

International Sales Division
Akandevvej 21
DK-2700 · Brønshøj · Denmark
Phone: +45 38 27 38 27
Phone (dir.): +45 38 27 21 64
Fax: +45 38 27 27 11
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e-mail: rint@rint.dk
http://www.radiometer.com

November 9, 2007
SKV

Декларация о надежном использовании оборудования Radiometer

Анализаторы фирмы Radiometer создаются при использовании самых передовых методов производства. Оборудование разрабатывается и тестируется вместе с **оригинальными расходными материалами фирмы Radiometer**, такими как электроды, мембраны, реактивы, и принимаются только точные допуски.

Это известный клинический факт, что точные результаты газов крови являются решающим фактором когда используются в качестве диагностических инструментов. Фактически, лучше не иметь никакого результата газов крови чем иметь неточный результат.

Чтобы гарантировать точные и надежные результаты выдаваемые анализаторами, **необходимо использовать только оригинальные расходные материалы фирмы Radiometer.**

Помимо вышеупомянутого, в результате использования на газовых анализаторах фирмы Radiometer (серии ABL) расходных материалов других фирм (Non-Radiometer) могут возникнуть многочисленные проблемы, и в связи с этим мы должны подчеркнуть важность использования на анализаторах **только расходных материалов фирмы Radiometer.**

Ниже приведен общий перечень проблем, которые могут быть вызваны использованием расходных материалов других фирм (Non-Radiometer). Это общие проблемы и они относятся к большинству анализаторов фирмы Radiometer.

1. Отклонение и неточность в результатах
2. Остаток между измерениями искажающий результаты
3. Разрушение фермента
4. Осадок/осаждение, загрязнение
5. Высокий дрейф при калибровках
6. Снижение производительности анализатора, длительный простой, укороченный жизненный цикл, неверные результаты и повторные измерения
7. Завышение контрольного диапазона при проведении Контроля Качества
8. Потеря уверенности в результатах и повторение измерений
9. Увеличение ежегодных затрат

Помните, что безопасность пациентов является наиболее важным направлением в современном медицинском здравоохранении, и для пациенты находящиеся в критическом состоянии нуждаются в получении точных результатов газов крови.

Best regards
RADIOMETER MEDICAL ApS
International Sales Division

Simon Kvetny
Regional Manager

Перевод с английского языка на русский язык проверен штатным переводчиком
Отдела переводов Торгово-промышленной Палаты Республики Молдова
Натальей Пясецкой
Кишинэу/ Молдова, 03.11.2008 г.





By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Radiometer Medical ApS
Åkandevvej 21
Brønshøj
2700
Denmark

Holds Certificate Number:

MD 672317

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacture, installation and servicing of blood gas analysers, transcutaneous blood gas and pulse oximetry monitors, fluorescence immunoassay analysers, blood collection devices and associated reagents, solutions, calibrators, controls, accessories and clinical laboratory information systems.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-09-11

Latest Revision Date: 2020-12-14

Effective Date: 2020-12-16

Expiry Date: 2023-12-15

Page: 1 of 2



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An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)1345 080 8000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 7AL, UK.
A Member of the BSI Group of Companies.



Certificate No: **MD 672317**

Location

Radiometer Medical ApS
Åkandevvej 21
2700 Brønshøj
Denmark

Registered Activities

Design, development, manufacture, installation and servicing of blood gas analysers, transcutaneous blood gas and pulse oximetry monitors, fluorescence immunoassay analysers, blood collection devices and associated reagents, solutions, calibrators, controls, accessories and clinical laboratory information systems.

Radiometer Medical ApS
Indian Development Center hosted by
Beckman Coulter India Pvt. Ltd
Building 6A, Unit 401 & 402 and 501 & 502
RMZ Eco World
Sarjapura Marathalli Outer Ring Road
Bengaluru
560103
India

Design and development of software for blood gas analysers, immunoassay analysers and point-of-care systems.

Original Registration Date: 2017-09-11

Latest Revision Date: 2020-12-14

Effective Date: 2020-12-16

Expiry Date: 2023-12-15

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A Member of the BSI Group of Companies.



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

Name	Ref. No.	GMDN	CE-mark
S8375 Cleaning solution with additive	944-126	30210	2008-12
S1820 Calibration solution 1	944-128	35933	2004-12
S1830 Calibration solution 2	944-129	35933	2004-12
S4980 Rinse solution	944-132	30210	2004-12
S1827 Calibration Solution 1	944-133	35933	2006-11
S1837 Calibration Solution 2	944-134	35933	2006-11
S8377 Cleaning Met II Solution	944-136	30210	2006-11
S4987 Rinse solution II	944-159	30210	2006-11

Issuance:

Name: Gitte Juel Friis
Title: Director Regulatory Affairs

Place: Copenhagen, Denmark

Signature:

Gitte Juel Friis

Date:

2014-03-25

[Signature]



EU Declaration of Conformity

Radiometer Medical A/S
Åkandevvej 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:

Kirsten Rønø



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: ABL700 and ABL800 series

Model Name	Article No.	Ref. No.	GMDN Code*	From Serial/ LOT No.
ctHb Calibration Solution	S7770	944-021	35933	Lot 30 onward

*: 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: Pierre Pelletier
Title: Regulatory Affairs Manager

Place: Copenhagen, Denmark

Signature:

Date: 2007-10-22



EU Declaration of Conformity

Radiometer Medical A/S
Åkandevvej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

S7745 AutoCheck5+ – Level 2

REF 944-075 from LOT 72 and onward

delivered from Radiometer Medical A/S after 2003-10-27, 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
Åkandevvej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

D711 Membrane box for E1001 electrode – Ref

REF 942-058 from LOT 194 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:

Kirsten Rønø



EU Declaration of Conformity

Radiometer Medical A/S
Åkandevvej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

D788 Membrane box for E788 electrode – $p\text{CO}_2$

REF 942-063 from LOT 65 and onward

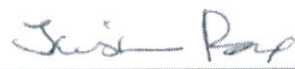
complies with the provisions in the directive:

98/79/EC (IVDD) Annex III

Issued (place): Copenhagen

Date: December 4, 2003 by: Kirsten Rønø

Director of Quality

Signature: 



EU Declaration of Conformity

Radiometer Medical A/S
Åkandevvej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

D799 Membrane box for E799 electrode – pO_2

REF 942-064 from LOT 56 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:

Kirsten Rønø



EU Declaration of Conformity

Radiometer Medical A/S
Åkandevvej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

D722 Membrane box for E722 electrode – K⁺

REF 942-059 from LOT 66 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:

Kirsten Rønø



EU Declaration of Conformity

Radiometer Medical ApS
Åkandevej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

D755 Membrane box for E755 electrode – Na⁺

REF 942-062 from LOT 63 and onward

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

98/79/EC (IVDD) Annex III

Issued (place): Copenhagen

Date: February 18, 2004 by: Kirsten Rønø

Director of Quality

Signature: 

RADIOMETER
COPENHAGEN 



EU Declaration of Conformity

Radiometer Medical A/S
Åkandevvej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

D744 Membrane box for E744 electrode – Cl⁻

REF 942-061 from LOT 42 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:

Kirsten Rønø



EU Declaration of Conformity

Radiometer Medical A/S
Åkandevej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

D733 Membrane box for E733 electrode – Ca^{2+}

REF 942-060 from LOT 55 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:



EU Declaration of Conformity

Radiometer Medical A/S
Åkandevej 21
DK-2700 Brønshøj

takes responsibility in declaring that the following product(s)

D7066 Membrane box for E7066 electrode – Glu

REF 942-065 from LOT 243 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: 

