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Location: Moldova

RADIOMETER

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

To whom it may concern

April 15, 2010

AUTHORIZATION

Hereby we, company Radiometer Medical ApS, Aakandevej 21, DK-2700 Bronshoj, 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

RADIOMETER MEDICAL ApS International Sales Division

Simon Kvetny
Director of Sales, CIS

"ECHIPAMED-PLUS" IDNO 1003600077677

RADIOMETER MEDICAL ApS

RADIOMETER COPENHAGEN

To whom it may concern

International Sales Division
Åkandevej 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

November 9, 2007
SKV

Declaration about secure use of Radiometer equipment

Radiometer analyzers are made by using the most advanced production methods. The equipment are developed and tested together with **the original Radiometer consumable items like electrodes, membranes, reagents** and only exact tolerances are accepted.

It is a known clinical fact that accurate blood gas results are crucial when used as diagnostic tools. In fact, it is better to have no blood gas result than to have an inaccurate result.

In order to guarantee proper and secure results from the analyzer **only the original Radiometer consumable must be used**.

Besides that above mentioned, numerous problems may arise from using non-Radiometer consumable items on the Radiometer blood gas analyzers (ABL series), and as such we must emphasize the importance of using **only Radiometer consumable items on the analyzers**.

Below is a general list of problems that may be caused by the use of non-Radiometer consumable items. This is a general and it applies to most Radiometer analyzers.

1. Inaccuracy and Imprecision
2. Carry-over between measurements
3. Destruction of enzyme
4. Deposits/precipitation, clogging
5. High drift on calibrations
6. Decreased analyzer performance, long downtime, shorter lifetime, invalid results and repeated measurements
7. Excessive control ranges on QC
8. Lost confidence and repeat measurements
9. Increased yearly cost

Remember that patient safety is the most important area in modern health care, and among the critically ill patients the accurate blood gas results are necessary.

Best regards
RADIOMETER MEDICAL ApS
International Sales Division

RADIOMETER MEDICAL ApS International Sales Division

Simon Kvelin
Regional Manager

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RADIOMETER MEDICAL ApS

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November 9, 2007
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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. Завышенние 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

REPUBLICA MOLDOVA Nr.2 CAMERA DE COMERȚ ȘI INDUSTRIE

«ECHIPAMED-PLUS» REPUBLICA MOLDOVA, MUN. CHIȘINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ OMG 1003600077671

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.

bsi.

By Royal Charter

Certificate of Registration

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

This is to certify that:

Radiometer Medical ApS
Åkandevej 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

...making excellence a habit.™

Certificate No: **MD 672317**

Location	Registered Activities
Radiometer Medical ApS Åkandevej 21 2700 Brønshøj Denmark	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

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

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

REPUBLICA MOLDOVA mun.CHIŞINAU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ECHIPAMED-PLUS" IDNO 1003600077677

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:

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

RADIOMETER COPENHAGEN

RADIOMETER COPENHAGEN

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: 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
Åkandevej 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

REPUBLICA MOLDOVA mun. CHIŞINĂU. SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TEHNIPAMED-PLUS" IDNO 1003600077677