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

Digitally signed by Iurchevici Valeriu
Date: 2020.11.10 11:07:15 EET
Reason: MoldSign Signature
Location: Moldova

"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

M10

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

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
2700 Brønshøj
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 and manufacture and servicing of blood gas analysers, transcutaneous blood gas and pulse oximetry monitors, fluorescence immunoassay analysers, arterial blood samplers and associated reagents, solutions, calibrators, controls, accessories and clinical laboratory information systems.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-09-11
Latest Revision Date: 2019-02-20

Effective Date: 2017-12-16
Expiry Date: 2020-12-15

UKAS MANAGEMENT SYSTEMS 003

...making excellence a habit.™

Certificate No: **MD 672317**

Location	Registered Activities
Radiometer Medical ApS Åkandevej 21 2700 Brønshøj Denmark	Design, development and manufacture and servicing of blood gas analysers, transcutaneous blood gas and pulse oximetry monitors, fluorescence immunoassay analysers, arterial blood samplers and associated reagents, solutions, calibrators, controls, accessories and clinical laboratory information systems.
Radiometer Medical ApS Priorparken 341 2650 Brondby Denmark	Warehousing
India Development Center (IDC) Building 6A Unit 401&402 and 501&502 RMZ Eco World Sarjapur Marathalli Outer Ring Road Bengalaru 560103 India	Design, development and manufacture and servicing of blood gas analysers, transcutaneous blood gas and pulse oximetry monitors, fluorescence immunoassay analysers, arterial blood samplers and associated reagents, solutions, calibrators, controls, accessories and clinical laboratory information systems.

Original Registration Date: 2017-09-11
Latest Revision Date: 2019-02-20

Effective Date: 2017-12-16
Expiry Date: 2020-12-15

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:
ABL80 FLEX CO-OX with Software v1.36 or higher for FLEX CO-OX configuration
ABL80 FLEX CO-OX with Software v1.50 or higher for OSM configuration
ABL80 FLEX CO-OX with Software v2.0 or higher for RiliBAEK configuration

Name	Ref. No.	GMDN	CE-mark
ABL80 FLEX CO-OX Analyzer	393-841	30847	2008-09
ABL80 FLEX CO-OX Capillary Adapters	906-025	37565	2008-09
ABL80 FLEX CO-OX Fluidics Kit	905-889	31336	2008-09
ABL80 FLEX CO-OX Sensor Cassettes			
ABL80 SC80 CO-OX	945-700	30201	2008-09
ABL80 SC80 CO-OX	945-701	30201	2008-09
ABL80 SC80 CO-OX	945-702	30201	2008-09
ABL80 SC80 CO-OX	945-703	30201	2008-09
ABL80 SC80 CO-OX	945-704	30201	2008-09
ABL80 SC80 CO-OX	945-705	30201	2008-09
ABL80 SC80 CO-OX	945-706	30201	2008-09
ABL80 SC80 CO-OX	945-707	30201	2008-09
ABL80 SC80 CO-OX	945-708	30201	2008-09
ABL80 SC80 CO-OX	945-709	30201	2008-09
ABL80 SC80 CO-OX	945-710	30201	2008-09
ABL80 SC80 CO-OX	945-711	30201	2008-09
ABL80 SC80 CO-OX	945-712	30201	2008-09
ABL80 SC80 CO-OX	945-713	30201	2008-09
ABL80 SC80 CO-OX	945-714	30201	2008-09
ABL80 SC80 CO-OX	945-715	30201	2008-09

Name	Ref. No.	GMDN	CE-mark
ABL80 SC80 CO-OX	945-716	30201	2008-09
ABL80 SC80 CO-OX	945-717	30201	2008-09
ABL80 SC80 CO-OX	945-718	30201	2008-09
ABL80 SC80 CO-OX	945-719	30201	2008-09
ABL80 SC80 CO-OX	945-720	30201	2008-09
ABL80 SC80 CO-OX	945-721	30201	2008-09
ABL80 SC80 CO-OX	945-722	30201	2008-09
ABL80 SC80 CO-OX	945-723	30201	2008-09
ABL80 SC80 CO-OX	945-724	30201	2008-09
ABL80 SC80 CO-OX	945-725	30201	2008-09
ABL80 SC80 CO-OX	945-726	30201	2008-09
ABL80 SC80 CO-OX	945-727	30201	2008-09
ABL80 SC80 CO-OX	945-728	30201	2008-09
ABL80 SC80 CO-OX	945-729	30201	2008-09
ABL80 SC80 CO-OX	945-730	30201	2008-09
ABL80 SC80 CO-OX	945-731	30201	2008-09
ABL80 SC80 CO-OX	945-732	30201	2008-09
ABL80 SC80 CO-OX	945-733	30201	2008-09
ABL80 SC80 CO-OX	945-734	30201	2008-09
ABL80 SC80 CO-OX	945-735	30201	2008-09
ABL80 SC80 CO-OX	945-806	30201	2012-09
ABL80 SC80 CO-OX	945-843	30201	2012-09
ABL80 FLEX CO-OX Solution Pack			
ABL80 SP80 CO-OX	944-252	35933	2010-01
ABL80 SP80 CO-OX	944-341	35933	2010-11
ABL80 SP80 CO-OX	944-350	35933	2011-11
ABL 80FLEX CO-OX Cleaning Pack			
SP80 Cleaning Pack	920-753	30210	2010-01
ABL80 CO-OX Cleaning Cassette	920-754	30201	2010-01

Issuance:

Name: Gitte Juel Friis
Title: Director Regulatory Affairs

Place: Copenhagen, Denmark

Signature: Gitte Juel Friis

Date: 2014-03-25