Digitally signed by Iurchevici Valeriu
Date: 2019.03.05 12:41:45 EET
Reason: MoldSign Signature
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 Kvamby
Director of Sales - CS

REPUBLICA MOLDOVA MUN. CHIȘINĂU. SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ECHIPAMED-PLUS" IDNO 1003600077677

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

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 13485:2003 for the following scope:

Design, development and manufacture 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: 2017-12-04

Effective Date: 2017-12-16
Expiry Date: 2019-02-28

UKAS MANAGEMENT SYSTEMS 003

...making excellence a habit.™

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

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

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