

To whom it may concern

Radiometer Medical ApS
Åkandevej 21
2700 Brønshøj
Denmark
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CVR No. 27 50 91 85
www.radiometer.com

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



Simon Kyerby
Director of Sales



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
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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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
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)145 080 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**

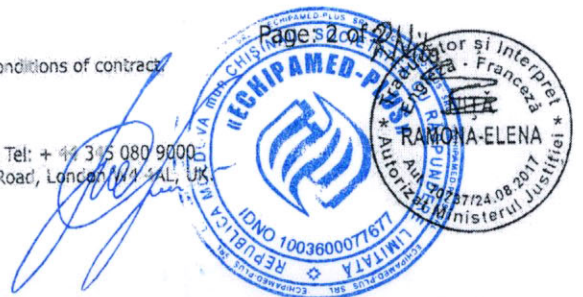
Location	Registered Activities
Radiometer Medical ApS Åkandevvej 21 2700 Brønshøj Denmark	Design, development, manufacture, installation and servicing of blood gas analysers, transcutaneous blood gas and pulse oximetry monitors, fluorescence immunoassay analysers, blood collection devices and associated 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
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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

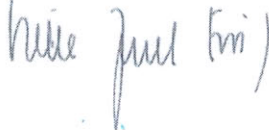
Product family: ABL800 FLEX blood gas, oximetry, electrolyte and metabolite analyzer

Name	Ref No.	GMDN	First CE-mark
ABL800 BASIC w/Autocheck	393-844	30847	2007-01
ABL800 FLEX w/Autocheck	393-845	30847	2006-09
ABL805 w/Autocheck & FLEXQ	393-805	30847	2007-01
ABL805 w/Autocheck	393-806	30847	2005-01
ABL810 BG only w/FLEXQ	393-803	30847	2007-12
ABL810 BG only w/Autocheck	393-804	30847	2005-12
ABL810, ABL820, ABL830 w/Autocheck & FLEXQ	393-820	30847	2005-12
ABL810, ABL820, ABL830 w/Autocheck	393-821	30847	2005-12
ABL815, ABL825, ABL835 w/Autocheck & FLEXQ	393-825	30847	2006-02
ABL815, ABL825, ABL835 w/Autocheck	393-826	30847	2004-09

Issuance:

Name: Gitte Juel Friis
Title: Director Regulatory Affairs

Place: Copenhagen, Denmark

Signature: 

Date: 2013-04-30

