

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](http://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





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.

*Gary E Slack*

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



...making excellence a habit.™

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](http://www.bsigroup.com/ClientDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)1908 800000  
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

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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

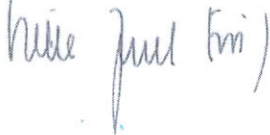
**Product family:** ABL800 FLEX blood gas, oximetry, electrolyte and metabolite analyzer

| 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

