

To whom it may concern

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

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  
Åkandevej 21  
2700 Brønshøj  
Denmark

Holds Certificate Number:

**MD 782470**

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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-02-16

Latest Revision Date: 2023-11-28

Effective Date: 2023-12-16

Expiry Date: 2026-12-15

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

Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 8460 780

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.





Certificate No: **MD 782470**

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 blood gas analysers, transcutaneous blood gas and pulse oximetry monitors, fluorescence immunoassay analysers and point of care systems.



Original Registration Date: 2023-02-16  
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Page: 2 of 2

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# EC Declaration of Conformity

## Radiometer Medical ApS

Åkandevvej 21

DK-2700 Brønshøj

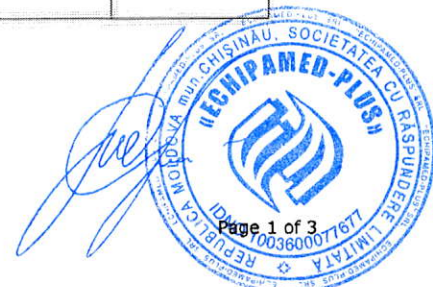
Denmark

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:** Electrodes

Name	Ref. No.	GMDN	CE-mark
E1001 Reference Electrode for ABL analyzers - Ref	945-603	59241	2003-12
E788 Electrode for ABL analyzers - $p\text{CO}_2$	945-612	54500	2004-02
E799 Electrode for ABL analyzers - $p\text{O}_2$	945-613	54501	2003-12
E777 Electrode for ABL analyzers - pH	945-614	54499	2004-06
E722 Electrode for ABL analyzers - $\text{K}^+$	945-615	52892	2003-12
E733 Electrode for ABL analyzers - $\text{Ca}^{2+}$	945-616	52874	2003-12
E744 Electrode for ABL analyzers - $\text{Cl}^-$	945-617	52876	2003-12
E755 Electrode for ABL analyzers - $\text{Na}^+$	945-618	52896	2003-12
E7077 Electrode for ABL analyzers - Lactate	945-619	30208	2003-12
E7066 Electrode for ABL analyzers - Glucose	945-620	53303	2003-12
E8088 CREA A Electrode	945-662	53252	2006-11
E8089 CREA B Electrode	945-663	53252	2006-11



**Issuance:**

Name: Anna Jessen

Place: Copenhagen, Denmark

Title: Sr. Director Regulatory Affairs

Signature:



Date: 14.04.2021