



Radiometer Medical ApS  
Åkandevej 21  
2700 Brønshøj  
Tlf.: +45 38 27 38 27  
Direkte:  
Mobil:  
Fax: +45 38 27 27 27  
CVR nr. 27509185  
www.radiometer.com

February 21, 2019

## To whom it may concern

This is to verify, that Radiometer Medical ApS has appointed the company;

BSI,  
Kitemark Court,  
Davy Avenue,  
Knowlhill,  
Milton Keynes, MK5 8PP,  
UK,

as its Notified Body

BSI has in that capacity issued the attached Certificate no. MD 672317, Effective Date: 2017-12-16, Quality Management system – ISO 13485:2016, covering the Radiometer site:

Radiometer Medical ApS  
Åkandevej 21  
2700 Brønshøj  
Denmark

Best regards,



Zaineb Alhilli  
Regulatory Affairs Coordinator  
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  
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

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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, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
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