

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Radiometer Medical ApS  
Åkandevej 21  
2700 Brønshøj  
Denmark

Facility ID Number: F000372

Holds Certificate No:

**MDSAP 695091**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-04-04

Effective Date: 2023-12-16

Expiry Date: 2026-12-15



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 695091**

## Registered Scope:

Design, development, manufacture, installation and service 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.



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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](https://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.