



# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Vitalograph (Ireland) Ltd  
Gort Road Business Park  
Ennis  
Co. Clare  
Ireland

Facility ID Number: F001465

Holds Certificate No: **MDSAP 700480**

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. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

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

**Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68, 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: 2019-10-17

Effective Date: 2022-10-17

Expiry Date: 2025-10-16

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BSI Group America Inc. is an MDSAP recognised auditing organization

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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.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 700480**

## Registered Scope:

Design, development, manufacture and distribution of Spirometers, Bacterial / Viral Filters, Mouthpieces, Nose clips, Peak Flow Meters, Cough sensor, Data Recording Devices, Aerosol Inhalation Training devices, Emergency Aspirators, Breath Gas Analysis devices and ECG devices and Pulmonary Function Test devices.

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