bsi.

By Royal Charter

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

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

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.

Original Registration Date: 2019-10-17 Effective Date: 2022-10-17 Expiry Date: 2025-10-16