

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Vitalograph (Ireland) Ltd**
Gort Road Business Park
Ennis
Clare
Ireland

DUNS Number: 21-968-3489

Holds Certificate No: **MDSAP 700480**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - 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

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.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-10-17

Effective Date: 2019-10-17

Expiry Date: 2022-10-16



BSI Group America Inc. is an MDSAP authorized auditing organization

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