

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

Holds Certificate Number:

MD 82182

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, 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, ECG devices and Pulmonary Function Test devices.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2004-03-03

Latest Revision Date: 2022-10-06

Effective Date: 2022-10-17

Expiry Date: 2025-10-16



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