



By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.

CE 85553

Issued To:

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

In respect of:

Those aspects of Annex V related to metrology in the manufacture of aerosol inhalation monitors, manual peak flow meters (GMDN 46872), breath gas analysis device (CO monitor) and pulmonary precision/calibration syringes (GMDN 17250)

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2004-07-07**

Date: **2019-07-22**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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A member of BSI Group of Companies.

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Supplementary Information to CE 85553

Issued To:

Vitalograph (Ireland) Ltd
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NBOG code(s)	Device description	Intended purpose
Class Im		
MD 1301	Respiratory Monitors BreathCO (carbon monoxide monitor), AIM (For Effective Inhaler Training On Dry Powder and Metered Dose Inhalers) Precision Syringe (air)	N/A

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