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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 00772**

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

In respect of:

The design, development and manufacture of electronic spirometers, peak flow meters, mouthpieces, cough monitors and cardio-pulmonary resuscitation equipment.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **14 July 1995** Date: **22 October 2015** Expiry Date: **13 July 2020**

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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

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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Supplementary Information to CE 85553

Issued To:

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

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

First Issued: **2004-07-07** Date: **2019-07-22** Expiry Date: **2024-05-26**

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