

# 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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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.

# 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):



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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.  
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# EC Certificate - Production Quality Assurance

## 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
<b>Class Im</b>		
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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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.