

# 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, Bacterial Viral Filters, peak flow meters, mouthpieces, cough monitors and ECG devices.**

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1995-07-14**

Date: **2020-06-08**

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

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Page 1 of 2

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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**Supplementary Information to CE 00772**

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

NBOG code(s)	Device Description	Intended purpose per IFU
<b>Class IIa</b>		
MD 1301	Spirometers	Not required for Class IIa
MD 1301	Respiratory Monitor Range	Not required for Class IIa
MD 0106	Respiratory Test Disposables	Not required for Class IIa
MD 1302	ECG	Not required for Class IIa
MD 1111	Software Spirotrac	Not required for Class IIa

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Page 2 of 2

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