

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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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.

Information and Contact: BSI, Bay Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 00772

Issued To:

Vitalograph (Ireland) Ltd
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Ennis
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NBOG code(s)	Device Description	Intended purpose per IFU
Class IIa		
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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