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By Royal Charter

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

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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Supplementary Information to CE 00772

Issued To:

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

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

First Issued: **1995-07-14** Date: **2020-06-08** Expiry Date: **2024-05-26**

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