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, ECG devices and Pulmonary Function Test 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: **2021-05-07** Expiry Date: **2024-05-26**

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Supplementary Information to CE 00772

Issued To:

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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
MD 1301	Pulmonary Function Test Devices	Not required for Class IIa

First Issued: **1995-07-14** Date: **2021-05-07** Expiry Date: **2024-05-26**

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Date:	**2021-05-07**
Issued To:	**Vitalograph (Ireland) Ltd** **Gort Road Business Park** **Ennis** **Co. Clare** **Ireland**

Subcontractor:	**Service(s) supplied**
Morgan Scientific, Inc. 151 Essex Street Haverhill MA 01832 USA	**Development** **Software**
Ningbo Tianyi Medical Appliance Co. Ltd No 788 Mozhi North Road Tourism Resort Dongqian Lake Ningbo 315121 China	**Manufacture**
Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II Zon Perdagangan Bebas Ipoh Perak 30020 Malaysia	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Shanghai Yaojia Medical Devices Co. Ltd. No. 15, Lane 399, Zhenzhongxin Rd. Xiaokunshan Town Songjiang District Shanghai 201614 China	**Manufacture**
Suntop CN Limited. Room 508, 509 Building B4 No.389, Zhaojiajing Road Songjiang District 201611 Shanghai People's Republic of China	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

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Date: **2021-05-07**

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Date	Reference Number	Action
14 July 1995		First issued
18 June 1996		Addition of Vitalograph Limited as a subcontractor
18 March 1999		Change of subcontractor list
30 November 2000		Change of scope
07 July 2004		Certificate renewal Change of scope New certificate format
25 July 2005		Certificate renewal
14 July 2010	7521644	Certificate renewal and revision of scope to clarify the inclusion of mouthpieces
03 July 2015	8284119	Certificate renewal. Addition of subcontractor, Shanghai Medical Specialties Ltd. for Manufacture
22 October 2015	8425043	Extension to Scope to include "cough monitors"
22 March 2019	9654503	Addition of Subcontractors: Shanghai Yaojia Medical Devices Co. Ltd., Synecco Co., Ltd, Plaxtron Industrial (M) Sdn. Bhd., Ningbo Tianyi Medical Appliance Co. Ltd & Gentian Services Ltd for Manufacture. Removal of Subcontractors: Shanghai Medical Specialties Ltd. And Vitalograph limited. Addition of "ECG devices" to the scope.

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Date	Reference Number	Action
25 March 2019	8951757	Traceable to NB 0086.
08 June 2020	9757940	Certificate Renewal. Clarification to Scope to include "Bacterial Viral Filters". Following Subcontractors were removed: Gentian Services Ltd, Synecco Co., Ltd Following subcontractor added: Suntop CN Ltd Device table added.
Current	3429526	Supplemented – Addition of Pulmonary Function Test Devices. Addition of Morgan Scientific, Inc as a subcontractor for software development.