

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

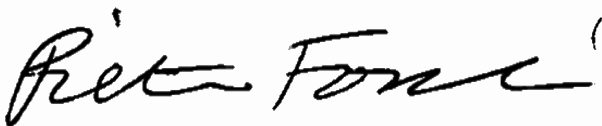
No. CE 85553
Issued To: **Vitalograph (Ireland) Ltd**
Gort Road Business Park
Ennis
Clare
Ireland

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 0086):



Pietro Foschi - Strategic Delivery Director

First Issued: **07 July 2004**

Date: **02 April 2015**

Expiry Date: **06 July 2019**

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Page 1 of 1

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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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Shanghai Medical Specialties Ltd. No. 599 Zhen Zhong Xin Road, Building No. 16, Xiao Kunshan Town, Songjiang District, Shanghai 201614 China	Manufacture
Vitalograph Limited Maids Moreton Buckinghamshire MK18 1SW United Kingdom	Administration & Complaints Warehousing

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 85553**
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Date	Reference Number	Action
07 July 2004		First issue
17 June 2009	7215186	Certificate Renewal Clarification of services supplied by the sub-contractor 'Vitalograph Limited' Alteration to certificate scope to reflect GMDN codes (supplied by the client) and descriptions
27 June 2014	8110842	Certificate Renewal without modifications
02 April 2015	8313182	Re-issue with amended scope and an additional subcontractor, 'Shanghai Medical Specialties Ltd., China' for manufacture.