

# 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  
Co. 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 2797):



Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2004-07-07**

Date: **2019-07-22**

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.

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## Supplementary Information to CE 85553

Issued To:

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

NBOG code(s)	Device description	Intended purpose
<b>Class Im</b>		
MD 1301	Respiratory Monitors  BreathCO (carbon monoxide monitor), AIM (For Effective Inhaler Training On Dry Powder and Metered Dose Inhalers)  Precision Syringe (air)	N/A

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say 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.

# EC Certificate - Production Quality Assurance

## Certificate History

Certificate No: **CE 85553**  
 Date: **2019-07-22**  
 Issued To: **Vitalograph (Ireland) Ltd**  
**Gort Road Business Park**  
**Ennis**  
**Co. Clare**  
**Ireland**

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.
25 March 2019	8951757	Traceable to NB 0086.
22 July 2019	9757917	Certificate Renewal & removal of critical sub-contractors.
<b>Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3</b>		
24 March 2022	3652870	Reduction of scope: Aerosol inhalation monitors, breath gas analysis device (CO monitor) and pulmonary precision/calibration syringes removed from the scope.

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24 March 2022

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

To whom it may concern,

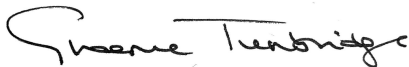
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

<b>Certificate</b>	<b>Directive and Annex</b>	<b>Reference Number</b>	<b>Changes approved</b>
CE 85553	93/42/EEC Annex V	3652870	Reduction of scope:  Aerosol inhalation monitors, breath gas analysis device (CO monitor) and pulmonary precision/calibration syringes removed from the scope.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge  
Senior Vice President, Medical Devices