By Royal Charter

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**

...making excellence a habit.™

EC Certificate - Production Quality Assurance

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
Class Im		
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

First Issued: **2004-07-07** Date: **2019-07-22** Expiry Date: **2024-05-26**

...making excellence a habit.™

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.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
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.

Inspiring trust for a more resilient world.

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 26th 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.

Certificate	Directive and Annex	Reference Number	Changes approved
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

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl