EC Certificate

Full Quality Assurance

No. CE 00772

Issued to:

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

In respect of:
The design, development and manufacture of electronic spirometers, peak flow meters, and cardio-pulmonary resuscitation equipment

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

Anne Boyd, Managing Director, BSI Product Services

First Issued: **14 Jul 1995** Date: **25 Jul 2005**

Expiration Date: **13 Jul 2010**

Conditions of Approval
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.
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.

Product Services

BSI Product Services
Maylands Avenue, Hemel Hempstead, Hertfordshire HP2 4SQ United Kingdom
Tel +44 (0)1442 230442 www.bsi-global.com
BSI Group Headquarters: 389 Chiswick High Road, London W4 4AL Tel: (0)208 996 9000

EC Certificate

List of Significant Subcontractors

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

Certificate No.	**CE 00772**
Date:	**25 Jul 2005**
Issued to:	**Vitalograph (Ireland) Ltd**
	Ennis

Subcontractor	**Service(s) supplied**
Vitalograph Limited Maids Moreton Buckinghamshire United Kingdom MK18 1SW	Administration & Complaints Warehousing

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PS089/0205/EP

EC Certificate

Production Quality Assurance

No. **CE 85553**

Issued to:

Vitalograph (Ireland) Limited

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, volumetric peak flow meters and precision/calibration syringes

On the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

Anne Boyd, Divisional Director, Product Services Operations

Conditions of Approval
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.
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 approval excludes Class 3 medical devices.

First Issued: **07 July 2004** Date: **07 July 2004**

Expiration Date: **06 July 2009**

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PS089