

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, peak flow meters, mouthpieces, cough monitors and cardio-pulmonary resuscitation equipment.

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **14 July 1995**

Date: **22 October 2015**

Expiry Date: **13 July 2020**

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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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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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Certificate History

Certificate No: **CE 00772**
 Date: **22 October 2015**
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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"

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