

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 00663
Issued To: **CareFusion**
22745 Savi Ranch Parkway
Yorba Linda
California
92887
USA

In respect of:

The design and manufacture of:

Adult, pediatric and neonatal ventilators and non-invasive ventilators (continuous positive airway pressure systems), patient breathing circuits, masks (nasal and full face), nasal prongs, and breathing gas mixers/blenders;
Respiratory monitors; flow sensors; spirometers; pulmonary function analyzers; cardio-pulmonary exercise testers; pulmonary/exercise testers; plethysmographs; and sleep analysis systems;

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: **23 May 1995**

Date: **18 May 2015**

Expiry Date: **22 May 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
Carclo Technical Plastics Shanghai Co., Ltd. 21 Lianxi Road, Huangdu Town Jiading District Shanghai 201804 China	Manufacture
CareFusion (Minneapolis) 17400 Medina Road, Suite 100 Minneapolis 55447 USA	Manufacture
CareFusion (Palm Springs) 1100 Bird Center Drive Palm Springs California 92262 USA	Manufacture

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Subcontractor:	Service(s) supplied
CareFusion Germany 234,GmbH Leibnizstrasse 7 97204 Hoechberg Germany	EU Representative
Productos Urologos de Mexico S.A. de C.V Cerrade Via de la Produccion No 85 Parque Industrial Mexicali III Baja California, CP 21397 Mexico	Manufacture

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