

EC Certificate - Full Quality Assurance System

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

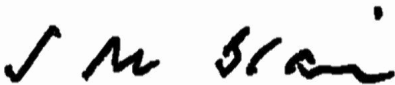
No. CE 667673
Issued To: **Medica Holdings, LLC**
5200 Meadows Road, Suite 150
Lake Oswego
Oregon
97035
USA

In respect of:

Design and manufacture of non-sterile, single patient, reusable positive expiratory pressure device intended to improve clearance of bronchial mucus secretions.

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):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2017-12-03**

Date: **2018-12-10**

Expiry Date: **2022-12-02**

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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 667673

Issued To:

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NBOG code(s)	Device Description	Intended purpose
Class IIa		
MD 0101	Oscillatory PEP Therapy Device	N/A for Class IIa devices

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List of Significant Subcontractors

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

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Oregon
97035
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Subcontractor:

Service(s) supplied

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

EU Representative

Pacific Integrated Manufacturing
Col Linda Vista
1089-1 Avenida Prolongacion M Juarez
Tijuana
Baja California
22129
Mexico

Finished Device Supplier

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: CE 667673
Date: 2018-12-10
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 USA

Date	Reference Number	Action
03 December 2017	8675084	First issue.
12 February 2018	8903631	Change of EU representative to Emergo Europe.
Current	9658709	Remove Engineered Medical Systems, Inc. and add Pacific Integrated Manufacturing as Finished Device Supplier.