By Royal Charter

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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Supplementary Information to CE 667673

Issued To:

Medica Holdings, LLC
5200 Meadows Road, Suite 150
Lake Oswego
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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

First Issued: **2017-12-03** Date: **2018-12-10** Expiry Date: **2022-12-02**

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List of Significant Subcontractors

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

Certificate No:	**CE 667673**
Date:	**2018-12-10**
Issued To:	**Medica Holdings, LLC** **5200 Meadows Road, Suite 150** **Lake Oswego** **Oregon** **97035** **USA**

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**

Issued To: **Medica Holdings, LLC**
5200 Meadows Road, Suite 150
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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.