By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 573041**

Issued To: **Mercury Medical**
11300 49th Street North
Clearwater
Florida
33762
USA

In respect of:

The Design and Manufacture of Manual T-Piece Ventilators, Hyperinflation Systems and Flow Safe Continuous Positive Airway Pressure devices.
Those aspects of Annex II related to metrology in the design and manufacture of Airway Pressure Monitors.

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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2011-05-13** Date: **2020-09-30** Expiry Date: **2024-05-26**

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List of Significant Subcontractors

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

Certificate No:	**CE 573041**
Date:	**2020-09-30**
Issued To:	**Mercury Medical** **11300 49th Street North** **Clearwater** **Florida** **33762** **USA**

Subcontractor:	**Service(s) supplied**
Cheen Houng Enterprise Co., Ltd. 23, Alley 11, Lane 65 San Dreen Street, Shulin (238) Taipei Taiwan	**Manufacture**
Emergo Europe Prinsessegracht 20 2515 AP The Hague The Netherlands	**EU Representative**
Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II Zon Perdagangan Bebas, Ipoh Perak 30020 Malaysia	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 573041**

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Date	Reference Number	Action
13 May 2011	7620561	First issue
27 January 2012	7708911	Extension of scope to include 'and Hyperinflation Systems' and changing the word 'Ventilator' to 'Ventilators'
25 July 2013	8022732	Extension of scope to include ', Flow Safe Continuous Positive Airway Pressure devices and EZFlow Continuous Nebulizers. Those aspects of Annex II related to metrology in the design and manufacture of Inspiratory Airway Pressure Meters and Airway Pressure Monitors'.
30 June 2015	8357659	Extension of scope to include 'Mapleson Anesthesia Circuits'
27 April 2016	8438470	Certificate Renewal
07 February 2019	9732317	Traceable to NB 0086.
Current	9783584	Certificate Renewal. Update of the legal address of the EU Representative Adventa Ltd from "Scanlan Group BV Postbus 7564, 1118 ZS Schiphol Triport, The Netherlands" to "Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, Netherlands". Removal of "EZFlow Continuous Nebulizers and Mapleson Anaesthesia Circuits" and "Inspiratory Airway Pressure Meters and" from scope.