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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EC Certificate - Full Quality Assurance System Certificate History

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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.
30 September 2020	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.

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Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
20 February 2023	3854982	Change of EU Representative's address. Removal of subcontractors page.

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20 February 2023

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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 573041	93/42/EEC Annex II excluding Section 4	3854982	Change of EU Representative's address from Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands to Emergo Europe, Westervoortsedijk 60, 6827 AT, Arnhem, The Netherlands. Removal of subcontractors page.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices