EC Certificate - Full Quality Assurance System

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

No. **CE 02054**

Issued To: **Millar Inc.**
6001-A Gulf Freeway
Houston
Texas
77023
USA

In respect of:

The design and manufacture of sterile catheter mounted pressure transducers, and associated control units.

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: **1998-08-24** Date: **2019-02-25** Expiry Date: **2023-08-23**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 02054**

Date: **2019-02-25**

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Houston
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Date	Reference Number	Action
24 August 1998		First issue
20 November 1998		Change of scope
05 February 1999		Change of scope
17 February 2004		Five years renewal Changes to List of Sub-contractors: Addition of MicroPaq and TriVirix as Manufacturing Sub-contractors New certificate format
20 August 2008	7243163	Certificate renewal Changes to the list of significant subcontractors: Removal of MicroPaq, TriViris, Ethox Corp, NAMSA Inc at 2261 Tracy Road, Northwood, NAMSA Inc at PO 71970, Cincinatti.
22 August 2013	7982551	Certificate renewal Change of scope to 'The design and manufacture of sterile catheter mounted pressure and velocity transducers, and associated control units' Addition of 'EMERGO EUROPE' as EU Representative.

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Date	Reference Number	Action
17 July 2014	8184301	Change of company name from 'Millar Instruments Inc.' to 'Millar Inc.'
18 April 2017	8718613	Removal of velocity transducers from the scope and change of Emergo Europe's address from Molenstraat 15, 2513 BH The Hague, Netherlands to Prinsessegracht 20, 2514 AP The Hague, Netherlands.
03 August 2018	8892474	Renewal
21 February 2019	8993161	Removal of Steritec, Inc subcontractor Addition of Sterigenics Subcontractor
25 February 2019	7781675	Traceable to NB 0086.

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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		
06 August 2021	3374714	Removal of subcontractor 'Sterigenics US,LLC' and addition of 'LEMCO Enterprises Inc.' as subcontractor for ETO sterilization. Scope reduced from 'The design and manufacture of sterile catheter mounted pressure transducers, and associated control units' to 'The design and manufacture of sterile catheter mounted pressure transducers'. The associated control units are removed from the scope.
17 May 2024	3774758	Change of manufacturer address to 11950 North Spectrum Blvd, Pearland, Texas, 77047, USA Removal of critical subcontractor and crucial supplier pages

Inspiring trust for a more resilient world.

17 May 2024

Millar Inc.
11950 North Spectrum Blvd
Pearland
Texas
77047
USA

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 02054	93/42/EEC Annex II excluding Section 4	3774758	Change of manufacturer address to 11950 North Spectrum Blvd, Pearland, Texas, 77047, USA Removal of critical subcontractor and crucial supplier pages

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