EC Design-Examination Certificate

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

No. **CE 560858**

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

In respect of:

Mikro-Cath Mikro-Tip Pressure Transducer Catheter

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: **2010-09-10** Date: **2021-05-03** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 560858

Issued To:

Millar Inc.
6001-A Gulf Freeway
Houston
Texas
77023
USA

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
825-0101	Mikro-Cath Pressure Sensor Transducer	825-0101	The Mikro-Cath is classified as surgically invasive device intended for short term use specifically to directly monitor blood pressure in the cardiovascular system and compartmental and airway pressure in the human body	Class III

First Issued: **2010-09-10** Date: **2021-05-03** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 560858

Issued To:

Millar Inc.
6001-A Gulf Freeway
Houston
Texas
77023
USA

History of Certificate

Date	Reference Number	Action
10 September 2010	10115662	First issue
17 July 2014	10149656	Change of company name from 'Millar Instruments Inc.' to 'Millar Inc.'
09 July 2015	10155418	Certificate Renewal
25 February 2019	7781675	Traceable to NB 0086.
09 April 2020	3091309	Review of changes related to the 5-year cycle. Addition of previously reviewed extension to scope. Addition of device table
08 December 2020	3217667	Certificate Renewal
Current	3405342	Design change for new radio-opaque marker, and epoxy change.

First Issued: **2010-09-10** Date: **2021-05-03** Expiry Date: **2024-05-26**

...making excellence a habit.™

By Royal Charter

Supplementary Information to CE 560858 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

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

Date: 27 March 2025

Changes Approved:

Date	Reference Number	Action
27 March 2025	3774906	Change of a material used for Mikro-Cath Pressure Sensor Transducer. Change of manufacturer address to 11950 North Spectrum Blvd, Pearland, Texas, 77047, USA

Inspiring trust for a more resilient world.

27 March 2025

Millar Inc.
11950 North Spectrum Blvd
Pearland
Texas
77047
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

The transitional provisions specified in IVDR Article 110(3) (as amended by (EU) 2024/1860) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

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) or under IVDR Article 110(3), as applicable, and as per the guidance provided in MDCG 2020-3/MDCG 2022-6.

The related certificate specified below continues to remain valid and devices can be placed on the market based on this certificate as long as the manufacturer complies with the conditions specified in Section 3c of Article 120 of MDR or in Section 3c of Article 110 of IVDR, as applicable.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 560858	93/42/EEC Annex II Section 4	3774906	Change of a material used for Mikro-Cath Pressure Sensor Transducer. Change of manufacturer address to 11950 North Spectrum Blvd, Pearland, Texas, 77047, USA

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

BSI Group The Netherlands B.V. T: +31 20 346 0780
Say Building info.nl@bsigroup.com
John M. Keynesplein 9 bsigroup.nl
1066 EP Amsterdam
The Netherlands