

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: **2020-12-08**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Supplementary Information to CE 560858

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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

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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
Current	3217667	Certificate Renewal

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