

UKCA Design-Examination Certificate

Part II of The Medical Devices Regulations 2002, Annex II Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No.**UKCA 778736****Issued To:**

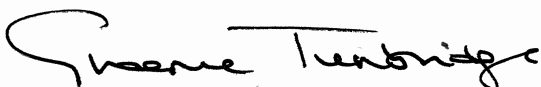
**Millar Inc.
11950 North Spectrum Blvd
Pearland
Texas
77047
USA**

In respect of:

Mikro-Cath Mikro-Tip Pressure Sensor Transducer

BSI has performed a design examination of the above devices in accordance with Part II of The Medical Devices Regulations 2002, Annex II Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The design conforms to the requirements of this regulation. For the placing on the market of these products an Annex II (modified as described above) excluding Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: **2023-06-23**

Date: **2025-03-31**

Expiry Date: **2025-12-07**

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Page 1 of 3

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

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

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.

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Supplementary Information to UKCA 778736

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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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Certificate History

Date	Reference Number	Action
2023-06-23	3767292	First Issue; Traceable to CE 560858.
Current	30251602	Change of a material used for Mikro-Cath Pressure Sensor Transducer. Change of manufacturer address to 11950 North Spectrum Blvd, Pearland, Texas, 77047, USA.

First Issued: **2023-06-23**Date: **2025-03-31**Expiry Date: **2025-12-07**

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Page 3 of 3

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