



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Emergo Asia Pacific Pty Ltd T/a Emergo Australia

for approval to supply

Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Mikro-Cath Pressure Transducer - Transducer, pressure, catheter tip

ARTG Identifier	388249
ARTG Start Date	10/05/2022
Product Category	Medical Device Included Class III
GMDN	15071
GMDN Term	Transducer, pressure, catheter tip
Intended Purpose	The catheter is a single-use catheter intended to be used for medical research and diagnostic purposes. The catheter is indicated to measure cardiovascular, intra-compartmental, and airway pressures in the human body. The catheter is used as a minimally invasive device under short term limited body contact (<24 hours). The typical cardiovascular application will be through the femoral artery with the use of an additional guiding catheter. The catheter may be introduced into the targeted muscle compartment through an introducer. The catheter may be introduced into the respiratory system through an existing orifice.

Manufacturer Details	Address	Certificate number(s)
Millar Inc	6001-A Gulf Freeway Houston , Texas , 77 023 United States Of America	DV-2021-MC-06908-1

ARTG Standard Conditions

The above Medical Device Included Class III has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Mikro-Cath Pressure Transducer - Transducer, pressure, catheter tip

Functional Description	The catheter is fitted with an ultra-miniature pressure sensor near the distal end. The sensor is side mounted at the catheter tip. The proximal end terminates in a connector. The pressure sensor produces an electrical output signal which varies in direct proportion to the magnitude of sensed pressure or sound. Extension cables are available for connection between the pressure connector and the pressure control unit. Cables may be sterilized.
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Variant Information

Description	Range
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Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

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