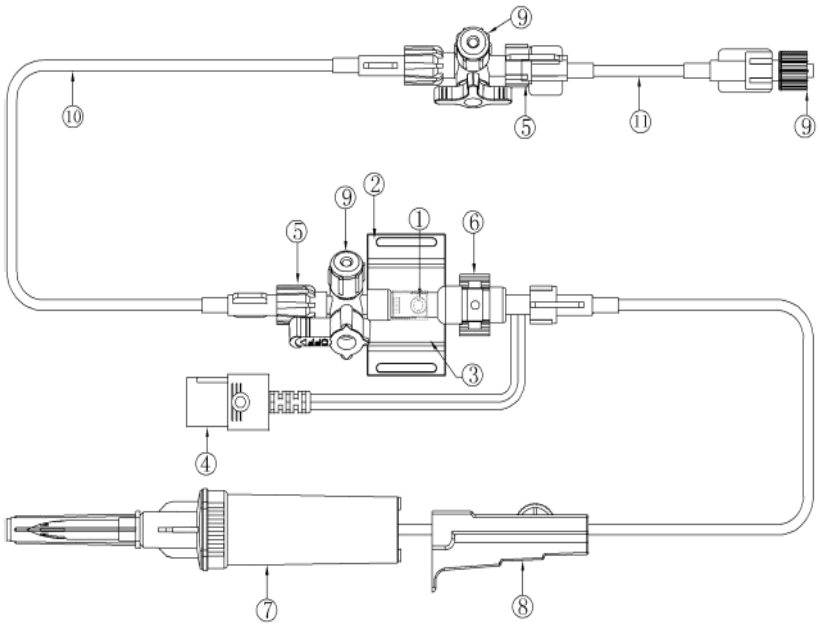
SecurMed 稳正医疗		File No	CM-26052201
		Version	A0
Title	Technical Data Sheet	Date	2025.5.22
		Page	1/1

Caremed P/N: ID-BBD

Description: B.BRAUN disposable IBP transducer, double Channel

1, Connector

2, Structure:



1——Pressure sensor chip；
2——Plastic housing；
3——Plastic cover；
4——Signal output cable；
5——Stopcock;
6——Flush device
7——Perfusion apparatus；
8—— Flow regulator
9——Cap；
10——Long connecting pipe；
11—— Short connecting pipe

3, Size requirement：
Hose Length: 20 +130+150 cm
Infusion tube Diameter: outer diameter 4.00±0.10mm, inner diameter 2.85±0.10mm.

4, Package:
25pcs per box,100pcs per carton. (Any special size requirement, please inform)

Digitally signed by Volcovschi Mihai
Date: 2026.05.22 10:50:17 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

5.0 Technical requirement:
Barometric pressure: 70~106Kpa
Relative humidity: 10~90% (non-condensing)
Operating pressure range: -50 ~ + 300 mmHg
Sensitivity: 5.0μV/V/mmHg ±3%
Nonlinearity and hysteresis: full-scale reading±1.5%
Input impedance: 1200Ω ~3200Ω
Output impedance: 300±5%
Zero pressure offset: -20mmHg~+20mmHg
Thermal offset shift: ≤±0.3mmHg/°C
Offset drift: After warm-up for 20 seconds, drift within 2 mmHg within 8 hours
Thermal span shift: ≤±0.1%/°C
Frequency response: Standard pressure set (48 "/ 12") is 40 Hz; Separate sensor > 200 Hz
Defibrillator withstand: Defibrillation depends on the final connection of the equipment.
Leakage current: Leakage current is dependent on the final connection of the equipment
Overpressure load: -400~+4000mmHg
Shock resistance : Withstand falling from one meter for three times
Light sensitivity: When exposed to a 3400°K tungsten light, candle light at 3000 feet, it's less than 1 mmHg
under rated voltage.
Contact with the human body: ≤168h
Storage and transport environment requirements: - 20 ° C~ + 60 ° C, < 90%(non-condensing), no corrosive gas and indoor
ventilation, and to avoid high temperature and cold.
Intra-system velocity
Flow 2-5mL/h
Intra-system velocity refers to the velocity under 6.00 VDC and 25°C, unless there are additional instructions.
Product shelf-life: 3 years.

Prepared By	罗颐希	Checked By	/	Approved By	肖心林

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 810636 R000

Manufacturer: Jiangxi Securmed Medical Technology Co., Ltd

Address:
1st floor and 3rd floor of Building 15th
(inside the Caremed
Factory),
Industrial Park Area
Xiajiang county, Ji'an City
Jiangxi
331409
China

Single Registration Number: CN-MF-000030117

EU Authorised Representative: Phoenix Medtech GmbH

Address:
Koenigsberger Strasse 11
64839
Muenster Hessen
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-07-17**

Current Issue Date: **2026-02-04**

Starting Validity Date: **2026-02-04**

Expiry Date: **2030-07-16**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 810636 R000

Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Transducers	It is used for measurement of central venous pressure and arterial pressure.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Connectors	Class IIa

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Current Issue Date: **2026-02-04**

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Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 810636 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2025-07-17	30190112	Issued
Current	30608294	Amended – Correct the reference number of the first issue; correction to the Legal manufacturer address. Supplemented – Addition of device category Transducers.

First Issue Date: **2025-07-17**

Current Issue Date: **2026-02-04**

Starting Validity Date: **2026-02-04**

Expiry Date: **2030-07-16**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation 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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
A Member of the BSI Group of Companies.