

Sensatronic GmbH Wismar	EU Declaration of Conformity	Dok.-Nr.: 724011 EU Declaration of Conformity_CBL.docx
	In accordance with Annex IV of Regulation (EU) 2017/745 on medical devices, amended by Regulation (EU) 2020/561	Page 1 of 2

EU Declaration of Conformity

We hereby declare under our sole responsibility, that the products listed below fulfill the requirements of the Regulation (EU) 2017/745 as well as corresponding regulatory requirements of the EU.

Manufacturers Name: SENSATRONIC GmbH

Manufacturers Address: AM RING 9, 23970 WISMAR, DE

SRN (Single Registration Number): DE-MF-000004927

Authorized Representative Name (if applicable): Not applicable

Authorized Representative Address (if applicable): Not applicable

Basic UDI-DI: See table below

Name of the Device (s): Extension cables for medical temperature probes

Product code: See table below

Intended Purpose: Extension cables for medical temperature probes are intended to connect a temperature probe to a monitoring device

Classification: Class I

Notified Body name: DNV MEDCERT GmbH

Notified Body Address: Pilatuspool 2, 20355 Hamburg, DE

Notified Body Identification number: 0482

Conformity assessment route: Sensatronic GmbH uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745:

According to (EU) 2017/745 Annex IX

This declaration of conformity is issued under the sole responsibility of **Sensatronic GmbH**; we hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by DNV Medcert GmbH.

All supporting documentation is retained at the premises of the manufacturer.

Signature:  **Sensatronic GmbH** Place and date (dd.mm.yyyy) of issue: Wismar, 2025-05-31

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Jens Schwarz

	geprüft: A. Sangani QMB	freigegeben: J. Schwarz Geschäftsleitung
Vorlage: 724001 MDR-Klassifizierung.doc	Erstellt: 2023-12-15	Sensatronic GmbH

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Attachment to Declaration of Conformity

Extension cables for disposable medical temperature probes

Reference number	Description	Basic-UDI-DI
013-00101	Temperature probe extension cable 3.0 m	426065138-TROA-Z5
013-00102	Temperature probe extension cable 5.0 m	426065138-TROA-Z5
013-00107	Temperature probe extension cable 3.0 m	426065138-TROA-Z5
013-00108	Temperature probe extension cable 5.0 m	426065138-TSKA-YQ
013-00109	Temperature probe extension cable 2.0 m	426065138-TSKA-YQ
013-00160	Temperature probe extension cable 3.0 m	426065138-TSKA-YQ
013-00161	Temperature probe extension cable 1.5 m	426065138-TROA-Z5
013-00162	Temperature probe extension cable 3.0 m	426065138-TROA-Z5
013-00163	Temperature probe extension cable 1.5- m	426065138-TROA-Z5

	geprüft: A. Sangani QMB	freigegeben: J. Schwarz Geschäftsleitung
Vorlage: 724001 MDR- Klassifizierung.doc	Erstellt: 2023-12-15	Sensatronic GmbH