

Sensatronic GmbH Wismar	EU Declaration of Conformity In accordance with Annex IV of Regulation (EU) 2017/745 on medical devices, amended by Regulation (EU) 2020/561	Dok.-Nr.: 724011 EU Declaration of Conformity_CBL.docx
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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
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 23970 Wismar F: +49 3841 2252442
 info@sensatronic.com
 Place and date (dd.mm.yyyy) of issue:
 Wismar, 2025-05-31

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

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

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