

## ***EU DECLARATION OF CONFORMITY***

**Document No. :** DOC-001-08

**Rev:** A7

**Manufacturer:** Orantech Inc.

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SRN : CN-MF-000013859

**EU- Representative:** Medten EU ApS

Oldenvej 33, 3490 Kvistgård, Denmark

SRN : DK-AR-000034434

**Product Name :** Temperature Flow Probe

**Product Models :** Please see the Annex I

**Basic UDI - DI:** 69416919ORANTECH21QV

**UMDNS Code :** 15237

**Classification - Annex VIII :** Class I, Rule 1

**Conformity Assessment Route :** Annex IX

We, Orantech Inc., herewith declare that this EU declaration of conformity is issued under the sole responsibility of the manufacturer. The products mentioned above are in conformity with the Medical Device Regulation 2017/745. All supporting documentations are retained under the premises of the manufacturer. We, the manufacturer, are exclusively responsible for doc.

**Standard Applied :**

EN ISO13485: 2016

EN 1041:2008+A1:2013

EN ISO 14971:2019

EN ISO 15223-1: 2021+A1:2025

Directive 2011/65/EU Annex II (EU) 2015/863

**Notified Body :** TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany

**CE mark :** 

**Place, Date of Issue :**

**Signature :** 

Shenzhen, May. 12<sup>th</sup>, 2025

**Position:** General Manager

## Annex I List Of Temperature Flow Probe

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
TSF-FP01-15	06941691968948	TSF-FP01-16	06941691982692	TSF-FP02-27	06941691977766
TSF-FP02-24	06941691977834	TSF-FP02-12	06941691977841	TSF-FP02-16	06941691977858
TSF-FP01-18	06941691977865	TSF-FP01-24	06941691977872	TSF-FP01-12	06941691978657