EU DECLARATION OF CONFORMITY

Document No.：DOC-001-08 **Rev:** A1

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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
DIRECTIVE 2011/65/EU

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

CE mark： CE

Valid Date From： 2020-01-10 **Valid Date Until：** 2024-05-26

Confirmation Letter No.：CL 098084 0005 Rev. 00

Valid Date From：2024-05-26 **Valid Date Until：**2028-12-31

Orantech
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Place, Date of Issue :

Shenzhen, Jun.21st, 2024

Signature : 薛素明

Position: General Manager

Annex I List Of ECG Leadwires

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
TSF-FP01-15	06941691968948				