

EU DECLARATION OF CONFORMITY

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Manufacturer: Orantech Inc.

Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community, GongMing, Guangming New District, Shenzhen, China.518106

SRN : CN-MF-000013859

EU- Representative: Medten EU ApS

Oldenvej 33, 3490 Kvistgård, Denmark

SRN : DK-AR-000034434

Product Name : Disposable Temperature Probe

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH14QY

UMDNS Code : 13125

Classification - Annex IX : Class IIb , Rule10

Conformity Assessment Route : Annex II

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 transposition national law,the provisions of Council Directive 93/42/EEC Concerning Medical Devices. 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

IEC 60601-1:2005/A1:2012

ISO 10993-5:2009

ISO 10993-10:2010

EN 62366-1:2015

ISO 80601-2-56:2017, AMD1:2018

IEC 60601-1-2: 2014

DIRECTIVE 2011/65/EU ANNEX II (EU) 2015/863

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

CE mark: 

EC Certificate No. : G1 098084 0003 Rev. 01

Valid Date From : 2020-01-10

Valid Date Until : 2024-05-26

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Add Zone#A,4F,1st Bld,7th Industrial Zone,Yulv Community,GongMing,Guangming New District,Shenzhen,China 518106

Confirmation Letter No. : CL 098084 0005 Rev. 00

Valid Date From : 2024-05-26

Valid Date Until : 2028-12-31

Place, Date of Issue :

Signature : 

Shenzhen, May. 12th, 2025

Position: General Manager

Annex I List of Temperature Probe

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
TSD-AT02-GS15	06941691980964	TSD-SL-AG30	06970706367834	TSD-TR-GS30	06970706367650
TSD-PM-LAG09	06941691974635	TSD-DG-AG30	06970706367827	TSD-IFN-GS30	06970706367643
TSD-DGD-GS15	06941691973713	TSD-MQ-AG30	06970706367810	TSD-SW-GS30	06970706367636
TSD-PM-PG09	06941691973539	TSD-PH-AG30	06970706367803	TSD-BLT-GS30	06970706367629
TSD-YSI-PG09	06941691973522	TSD-R20-AG30	06970706367797	TSD-AS-GS30	06970706367612
TSD-AT01-GS15	06941691969990	TSD-R10-AG30	06970706367780	TSD-MRB-GS30	06970706367605
TSD-OH-GS15	06941691958710	TSD-Y400-AG30	06970706367773	TSD-MRA-GS30	06970706367599
TSD-OHA-GS09	06941691957744	TSD-PM-AG09	06970706367766	TSD-SL-GS30	06970706367582
TSD-DGC-GS15	06941691957737	TSD-YSI-AG09	06970706367759	TSD-DG-GS30	06970706367575
TSD-OHA-GS30	06941691957720	TSD-JS-GS15	06970706367742	TSD-MQ-GS30	06970706367568
TSD-AS-GS15	06941691957713	TSD-DVC-GS15	06970706367735	TSD-PH-GS30	06970706367551
TSD-TR-AG30	06970706367902	TSD-DVB-GS15	06970706367728	TSD-R20-GS30	06970706367544
TSD-IFN-AG30	06970706367896	TSD-DVA-GS15	06970706367711	TSD-R10-GS30	06970706367537
TSD-SW-AG30	06970706367889	TSD-AT-GS15	06970706367704	TSD-Y400-GS30	06970706367520
TSD-BLT-AG30	06970706367872	TSD-DGB-GS15	06970706367698	TSD-PM-GS09	06970706367513
TSD-AS-AG30	06970706367865	TSD-DGA-GS15	06970706367681	TSD-YSI-GS09	06970706367506

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TSD-MRB-AG30	06970706367858	TSD-OHA-GS15	06970706367674	TSD-OH-GS30	06970706367667
TSD-MRA-AG30	06970706367841				