

EU DECLARATION OF CONFORMITY

Document No. : DOC-003-02

Rev: A3

Manufacturer: Orantech Inc.

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

SRN : CN-MF-000013859

EC- 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

EN ISO 10993-1:2009/AC:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2010

EN62366-1:2015

EN ISO 80601-2-56:2009

IEC 60601-1-2: 2014

IEC 60601-1:2005/A1:2012

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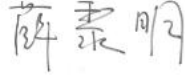
Add Zone#A,4F,1st Bld,7th Industrial Zone,Yulv Community,GongMing,Guangming New District,Shenzhen,China 518106

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, Aug. 27th, 2024

Position: General Manager

Annex I List of Temperature Probe

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
TSD-OHA-GS15	06970706367674	TSD-PH-AG30	06970706367803	TSD-MQ-AG30	06970706367810
TSD-DGA-GS15	06970706367681	TSD-YSI-GS09	06970706367506	TSD-DG-AG30	06970706367827
TSD-DGB-GS15	06970706367698	TSD-PM-GS09	06970706367513	TSD-SL-AG30	06970706367834
TSD-AT-GS15	06970706367704	TSD-OHA-GS09	06941691957744	TSD-YSI-PG09	06941691973522
TSD-DVA-GS15	06970706367711	TSD-AT01-GS15	06941691969990	TSD-PM-PG09	06941691973539
TSD-DVB-GS15	06970706367728	TSD-OH-GS30	06970706367667	TSD-DGD-GS15	06941691973713
TSD-DVC-GS15	06970706367735	TSD-BLT-AG30	06970706367872	TSD-DGB-GS30	06941691962076
TSD-JS-GS15	06970706367742	TSD-MRA-AG30	06970706367841	TSD-AS-GS30	06970706367612
TSD-AS-GS15	06941691957713	TSD-MRB-AG30	06970706367858	TSD-MRB-GS30	06970706367605
TSD-OH-GS15	06941691958710	TSD-SW-AG30	06970706367889	TSD-BLT-GS30	06970706367629
TSD-DGC-GS15	06941691957737	TSD-IFN-AG30	06970706367896	TSD-SW-GS30	06970706367636
TSD-Y400-GS30	06970706367520	TSD-TR-AG30	06970706367902	TSD-IFN-GS30	06970706367643
TSD-R10-GS30	06970706367537	TSD-YSI-AG09	06970706367759	TSD-TR-GS30	06970706367650
TSD-R20-GS30	06970706367544	TSD-PM-AG09	06970706367766	TSD-OHA-GS30	06941691957720
TSD-PH-GS30	06970706367551	TSD-Y400-AG30	06970706367773	TSD-PM-LAG09	06941691974635
TSD-MQ-GS30	06970706367568	TSD-R10-AG30	06970706367780	TSD-SL-GS30	06970706367582

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TSD-DG-GS30	06970706367575	TSD-R20-AG30	06970706367797	TSD-MRA-GS30	06970706367599
TSD-AT02-GS15	06941691980964				