

EU DECLARATION OF CONFORMITY

Document No. : DOC-003-02

Rev: A0

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

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

Orantech Inc.

T +86-755 2369 9939 **F** +86-755 2324 3594 **E** info@orantech.com **W** www.orantech.com

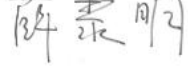
Add Zone#A,4F,1st Bld,7th Industrial Zone,Yulv Community,GongMing,Guangming New District,Shenzhen,China 518106

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, Jun.25th, 2024

Position: General Manager

Annex I List of Temperature Probe

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
TSD-OHA-GS15	06970706366529	TSD-YSI-GS09	06941691958757	TSD-MQ-AG30	06970706366987
TSD-DGA-GS15	06970706366530	TSD-PM-GS09	06941691958758	TSD-DG-AG30	06970706366988
TSD-DGB-GS15	06970706366531	TSD-OHA-GS09	06941691958759	TSD-SL-AG30	06970706366989
TSD-AT-GS15	06970706366532	TSD-AT01-GS15	06941691958776	TSD-YSI-PG09	06970706367006
TSD-DVA-GS15	06970706366533	TSD-OH-GS30	06941691958777	TSD-PM-PG09	06970706367007
TSD-DVB-GS15	06970706366534	TSD-PM-LAG09	06941691958778	TSD-DGD-GS15	06970706367008
TSD-DVC-GS15	06970706366535	TSD-BLT-AG30	06941691958787	TSD-DGB-GS30	06970706367010
TSD-JS-GS15	06970706366536	TSD-MRA-AG30	06970706366976	TSD-AS-GS30	06970706367019
TSD-AS-GS15	06970706366537	TSD-MRB-AG30	06970706366977	TSD-MRB-GS30	06970706366548
TSD-OH-GS15	06970706366538	TSD-SW-AG30	06970706366978	TSD-BLT-GS30	06970706366549
TSD-DGC-GS15	06970706366539	TSD-IFN-AG30	06970706366979	TSD-SW-GS30	06970706366550
TSD-Y400-GS30	06970706366540	TSD-TR-AG30	06970706366980	TSD-IFN-GS30	06970706366551
TSD-R10-GS30	06970706366541	TSD-YSI-AG09	06970706366981	TSD-TR-GS30	06970706366552
TSD-R20-GS30	06970706366542	TSD-PM-AG09	06970706366982	TSD-OHA-GS30	06970706366553
TSD-PH-GS30	06970706366543	TSD-Y400-AG30	06970706366983	TSD-PM-LAG09	06970706366554

Orantech Inc.

T +86-755 2369 9939 **F** +86-755 2324 3594 **E** info@orantech.com **W** www.orantech.com

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

TSD-MQ-GS30	06970706366544	TSD-R10-AG30	06970706366984	TSD-SL-GS30	06970706366546
TSD-DG-GS30	06970706366545	TSD-R20-AG30	06970706366985	TSD-MRA-GS30	06970706366547
TSD-PH-AG30	06970706366986				