

EU DECLARATION OF CONFORMITY

Document No. : DOC-003-01

Rev: B6

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 : Reusable Temperature Probe

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH09R7

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 : 薛永明

Shenzhen, Aug. 27th, 2024

Position: General Manager

Annex I List of Temperature Probe

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
TS-Y400-AS30	06970706366509	TS-PH-PG30	06970706367063	TS-DGB-PS15	06941691954828
TS-Y700-AS30	06970706366516	TS-MQ-PG30	06970706367070	TS-Y400S-PS30	06941691954835
TS-R10-AS30	06970706366523	TS-DG-PG30	06970706367087	TS-AS-PS15	06941691958727
TS-R20-AS30	06970706366530	TS-SL-PG30	06970706367094	TS-Y400-AG30	06970706366653
TS-PH-AS30	06970706366547	TS-MRA-PG30	06970706367100	TS-Y700-AG30	06970706366660
TS-MQ-AS30	06970706366554	TS-MRB-PG30	06970706367117	TS-R10-AG30	06970706366677
TS-DG-AS30	06970706366561	TS-PG-PG30	06970706367124	TS-R20-AG30	06970706366684
TS-SL-AS30	06970706366578	TS-BLT-PG30	06970706367131	TS-PH-AG30	06970706366691
TS-MRA-AS30	06970706366585	TS-SW-PG30	06970706367148	TS-MQ-AG30	06970706366707
TS-MRB-AS30	06970706366592	TS-IFN-PG30	06970706367155	TS-DG-AG30	06970706366714
TS-BLT-AS30	06970706366615	TS-TR-PG30	06970706367162	TS-SL-AG30	06970706366721
TS-SW-AS30	06970706366622	TS-Y400S-PG30	06941691954859	TS-MRA-AG30	06970706366738
TS-IFN-AS30	06970706366639	TS-Y400-PS30	06970706366806	TS-MRB-AG30	06970706366745
TS-TR-AS30	06970706366646	TS-Y700-PS30	06970706366813	TS-BLT-AG30	06970706366769
TS-P63SB-AS30	06941691947011	TS-R10-PS30	06970706366820	TS-SW-AG30	06970706366776
TS-ED-AS30	06941691954507	TS-R20-PS30	06970706366837	TS-IFN-AG30	06970706366783

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TS-EDA-AS30	06941691959229	TS-PH-PS30	06970706366844	TS-TR-AG30	06970706366790
TS-PH-AS75	06941691959236	TS-MQ-PS30	06970706366851	TS-Y400S-AG30	06941691963042
TS-AS-AS15	06941691960294	TS-SL-PS30	06970706366875	TS-Y400S-AS30	06941691954798
TSQ-AR01-OB	06970706367919	TS-MRA-PS30	06970706366882	TSQ-AR01-RR	06970706367971
TSQ-GE01-RR	06970706368008	TSQ-GE01-OB	06970706367940	TSQ-AR01-RR-S	06941691954149
TSQ-AR02-OB	06970706367926	TSQ-WA01-OB	06941691947073	TSQ-AR02-RR	06970706367988
TSQ-WA01-RR	06970706368015	TSQ-WA01-OB-S	06970706367957	TSQ-AR02-OB-S	06970706367933
TSQ-MR01-OB	06970706367964	TSQ-WA01-RR-S	06941691947080	TSQ-MR01-RR	06970706368022
TSQ-AR01-OB-S	06941691954132	TSQ-AR02-RR-S	06970706367995	TS-CM01-AG30	06941691981084
TS-DSA-PS15	06941691958987	TS-CM01-AS30	06941691981077	TS-OHA-PS30	06941691947042