

EU DECLARATION OF CONFORMITY

Document No. : DOC-003-01

Rev: C1

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 : 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+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
TS-SD02-PS16	06941691981527	TS-AS-PS15	06941691958727	TS-AS-PS30	06970706366905
TS-SD01-PS16	06941691981381	TS-Y400S-PG30	06941691954859	TS-MRB-PS30	06970706366899
TS-CM01-AS30	06941691981077	TS-ED-PG30	06941691954842	TS-MRA-PS30	06970706366882
TS-CM01-AG30	06941691981084	TS-Y400S-PS30	06941691954835	TS-SL-PS30	06970706366875
TS-BE04-PS15	06941691977391	TS-DGB-PS15	06941691954828	TS-DG-PS30	06970706366868
TS-ZN-AS30	06941691977131	TS-ED-PS30	06941691954811	TS-MQ-PS30	06970706366851
TS-FA-PS30	06941691975595	TS-ED-AG30	06941691954804	TS-PH-PS30	06970706366844
TS-BE01-PS15	06941691974666	TS-Y400S-AS30	06941691954798	TS-R20-PS30	06970706366837
TS-BE02-PS15	06941691974659	TS-ED-AS30	06941691954507	TS-R10-PS30	06970706366820
TS-CM01-PG30	06941691975069	TS-P63SB-PG30	06941691947059	TS-Y700-PS30	06970706366813
TS-CM01-PS30	06941691975038	TS-OHA-PS30	06941691947042	TS-Y400-PS30	06970706366806
TS-CM02-PS30	06941691975045	TS-P63SB-PS30	06941691947035	TS-TR-AG30	06970706366790
TS-CM03-PS10	06941691975052	TS-P63SB-AG30	06941691947028	TS-IFN-AG30	06970706366783
TS-CM-AG30	06941691974406	TS-P63SB-AS30	06941691947011	TS-SW-AG30	06970706366776
TS-AT01-PS15	06941691969983	TS-TR-PG30	06970706367162	TS-BLT-AG30	06970706366769

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TS-DGC-PS30	06941691966685	TS-IFN-PG30	06970706367155	TS-AS-AG30	06970706366752
TS-DGA-PS30	06941691966678	TS-SW-PG30	06970706367148	TS-MRB-AG30	06970706366745
TS-BE01-AS15	06941691966623	TS-BLT-PG30	06970706367131	TS-MRA-AG30	06970706366738
TS-PH-AS40	06941691966180	TS-PG-PG30	06970706367124	TS-SL-AG30	06970706366721
TS-CM-AS30	06941691964995	TS-MRB-PG30	06970706367117	TS-DG-AG30	06970706366714
TS-EDA-PS30	06941691964902	TS-MRA-PG30	06970706367100	TS-MQ-AG30	06970706366707
TS-MRA-AS60	06941691964186	TS-SL-PG30	06970706367094	TS-PH-AG30	06970706366691
TS-BE02-AS15	06941691964179	TS-DG-PG30	06970706367087	TS-R20-AG30	06970706366684
TS-DG-PG15	06941691961727	TS-MQ-PG30	06970706367070	TS-R10-AG30	06970706366677
TS-BT-PS15	06941691962625	TS-PH-PG30	06970706367063	TS-Y700-AG30	06970706366660
TS-DG-PS15	06941691961758	TS-R20-PG30	06970706367056	TS-Y400-AG30	06970706366653
TS-Y400S-AG30	06941691963042	TS-R10-PG30	06970706367049	TS-TR-AS30	06970706366646
TS-R10S-AG30	06941691963028	TS-Y700-PG30	06970706367032	TS-IFN-AS30	06970706366639
TS-DG-AG15	06941691961710	TS-Y400-PG30	06970706367025	TS-SW-AS30	06970706366622
TS-EDA-AG30	06941691961703	TS-JS-PS15	06970706367018	TS-BLT-AS30	06970706366615
TS-R10S-AS30	06941691963035	TS-DVC-PS15	06970706367001	TS-AS-AS30	06970706366608
TS-DG-AS15	06941691961697	TS-DVB-PS15	06970706366998	TS-MRB-AS30	06970706366592
TS-AS-AS15	06941691960294	TS-DVA-PS15	06970706366981	TS-MRA-AS30	06970706366585
TS-PH-AS75	06941691959236	TS-AT-PS30	06970706366974	TS-SL-AS30	06970706366578
TS-EDA-AS30	06941691959229	TS-DGA-PS15	06970706366967	TS-DG-AS30	06970706366561
TS-AT-PS15	06941691959038	TS-OH-PS30	06970706366950	TS-MQ-AS30	06970706366554

TS-DSB-PS15	06941691958994	TS-TR-PS30	06970706366943	TS-PH-AS30	06970706366547
TS-DSA-PS15	06941691958987	TS-IFN-PS30	06970706366936	TS-R20-AS30	06970706366530
TS-OHA-PS15	06941691958758	TS-SW-PS30	06970706366929	TS-R10-AS30	06970706366523
TS-OH-PS15	06941691958741	TS-BLT-PS30	06970706366912	TS-Y700-AS30	06970706366516
TS-DGC-PS15	06941691958734	TS-Y400-AS30	06970706366509	TSQ-AR01-RR-S	06941691954149
TSQ-AR01-OB-S	06941691954132	TSQ-WA01-RR-S	06941691947080	TSQ-WA01-OB	06941691947073
TSQ-MR01-RR	06970706368022	TSQ-WA01-RR	06970706368015	TSQ-GE01-RR	06970706368008
TSQ-AR02-RR-S	06970706367995	TSQ-AR02-RR	06970706367988	TSQ-AR01-RR	06970706367971
TSQ-MR01-OB	06970706367964	TSQ-WA01-OB-S	06970706367957	TSQ-GE01-OB	06970706367940
TSQ-AR02-OB-S	06970706367933	TSQ-AR02-OB	06970706367926	TSQ-AR01-OB	06970706367919
TS-FP01-AS30	06941691982609	TS-FP01-PS30	06941691982616	TS-FP02-13	06941691977827