

EU DECLARATION OF CONFORMITY

Document No. : DOC-003-01

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: Cables and Sensors B.V.

Zekeringstraat 21B , 1014 BM Amsterdam, Netherlands
SRN : NL-AR-000012545

Product Name : Temperature probe

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH09R7

UMDNS Code : 13125

Classification : Class IIa , Rule10 (Annex VIII of MDR 2017/745/EEC)

Conformity Assessment Route : According to Annex IX chapter I and III of MDR 2017/745/EEC

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 Medical Device Regulation, the provisions of council MDR 2017/745/EEC of 26 May, 2020 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 ISO 14971:2019	EN ISO 15223-1:2020
IEC 60601-1:2005/A1:2012	IEC 62366 : 2015
EN 1041:2008	EN ISO 10993-1:2018
ISO 80601-2-56:2017/Amd .1:2018[E]	EN ISO 10993-10:2010
EN ISO 10993-5:2009	

Notified Body : TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany

CE mark: 

EC Certificate No. : G1 098084 0003 Rev. 01

Valid Date From : 2020-01-10

Valid Date Until : 2024-05-26

Place, Date of Issue :

Signature : 

Shenzhen, July. 1st, 2021

Position: General Manager

Annex I List of Temperature probe

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
TS-Y400-AS30	6970706366509	TS-DGC-PS15	6941691958734	TS-DGA-PS15	6970706366967
TS-Y700-AS30	6970706366516	TS-OH-PS15	6941691958741	TS-DVA-PS15	6970706366981
TS-R10-AS30	6970706366523	TS-AT-PS15	6941691959038	TS-DVB-PS15	6970706366998
TS-R20-AS30	6970706366530	TS-OHA-PS15	6941691958758	TS-DVC-PS15	6970706367001
TS-PH-AS30	6970706366547	TS-DSA-PS15	6941691958987	TS-JS-PS15	6970706367018
TS-MQ-AS30	6970706366554	TS-DSB-PS15	6941691958994	TS-OHA-PS30	6941691947042
TS-DG-AS30	6970706366561	TS-BT-PS15	6941691962625	TS-DGB-PS15	6941691954828
TS-SL-AS30	6970706366578	TS-Y400-PG30	6970706367025	TS-Y400S-PS30	6941691954835
TS-MRA-AS30	6970706366585	TS-Y700-PG30	6970706367032	TS-AS-PS15	6941691958727
TS-MRB-AS30	6970706366592	TS-R10-PG30	6970706367049	TSD-MRA-AG30	6970706367841
TS-BLT-AS30	6970706366615	TS-R20-PG30	6970706367056	TSD-MRB-AG30	6970706367858
TS-SW-AS30	6970706366622	TS-PH-PG30	6970706367063	TSD-SW-AG30	6970706367889
TS-IFN-AS30	6970706366639	TS-MQ-PG30	6970706367070	TSD-IFN-AG30	6970706367896
TS-TR-AS30	6970706366646	TS-DG-PG30	6970706367087	TSD-TR-AG30	6970706367902
TS-P63SB-AS30	6941691947011	TS-SL-PG30	6970706367094	TSD-YSI-AG09	6970706367759
TS-ED-AS30	6941691954507	TS-MRA-PG30	6970706367100	TSD-PM-AG09	6970706367766
TS-Y400S-AS30	6941691954798	TS-MRB-PG30	6970706367117	TSD-Y400-AG30	6970706367773
TS-EDA-AS30	6941691959229	TS-PG-PG30	6970706367124	TSD-R10-AG30	6970706367780
TS-PH-AS75	6941691959236	TS-BLT-PG30	6970706367131	TSD-R20-AG30	6970706367797
TS-AS-AS15	6941691960294	TS-SW-PG30	6970706367148	TSD-PH-AG30	6970706367803
TSD-OHA-GS15	6970706367674	TS-IFN-PG30	6970706367155	TSD-MQ-AG30	6970706367810
TSD-DGA-GS15	6970706367681	TS-TR-PG30	6970706367162	TSD-DG-AG30	6970706367827
TSD-DGB-GS15	6970706367698	TS-Y400S-PG30	6941691954859	TSD-SL-AG30	6970706367834
TSD-AT-GS15	6970706367704	TSD-YSI-GS09	6970706367506	TS-Y400-AG30	6970706366653
TSD-DVA-GS15	6970706367711	TSD-PM-GS09	6970706367513	TS-Y700-AG30	6970706366660
TSD-DVB-GS15	6970706367728	TSD-OHA-GS09	6941691957744	TS-R10-AG30	6970706366677
TSD-DVC-GS15	6970706367735	TS-Y400-PS30	6970706366806	TS-R20-AG30	6970706366684
TSD-JS-GS15	6970706367742	TS-Y700-PS30	6970706366813	TS-PH-AG30	6970706366691
TSD-AS-GS15	6941691957713	TS-R10-PS30	6970706366820	TS-MQ-AG30	6970706366707
TSD-OH-GS15	6941691958710	TS-R20-PS30	6970706366837	TS-DG-AG30	6970706366714

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TSD-DGC-GS15	6941691957737	TS-PH-PS30	6970706366844	TS-SL-AG30	6970706366721
TSD-Y400-GS30	6970706367520	TS-MQ-PS30	6970706366851	TS-MRA-AG30	6970706366738
TSD-R10-GS30	6970706367537	TS-SL-PS30	6970706366875	TS-MRB-AG30	6970706366745
TSD-R20-GS30	6970706367544	TS-MRA-PS30	6970706366882	TS-BLT-AG30	6970706366769
TSD-PH-GS30	6970706367551	TS-MRB-PS30	6970706366899	TS-SW-AG30	6970706366776
TSD-MQ-GS30	6970706367568	TS-AS-PS30	6970706366905	TS-IFN-AG30	6970706366783
TSD-DG-GS30	6970706367575	TS-BLT-PS30	6970706366912	TS-TR-AG30	6970706366790
TSD-SL-GS30	6970706367582	TS-SW-PS30	6970706366929		
TSD-MRA-GS30	6970706367599	TS-IFN-PS30	6970706366936		
TSD-MRB-GS30	6970706367605	TS-TR-PS30	6970706366943		
TSD-BLT-GS30	6970706367629	TS-OH-PS30	6970706366950		
TSD-SW-GS30	6970706367636				
TSD-IFN-GS30	6970706367643				
TSD-TR-GS30	6970706367650				
TSD-OH-GS30	6970706367667				
TSD-DGB-GS30	6941691962076				
TSD-OHA-GS30	6941691957720				