

EU DECLARATION OF CONFORMITY

Document No. : DOC-009-01

Rev: A4

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 : Fitting/Adapters

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH20QT

UMDNS Code : 11726

Classification - Annex VIII : Class I, Rule 1

Conformity Assessment Route : Annex IX

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 2017/745. 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

DIRECTIVE 2011/65/EU

Notified Body : TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany

CE mark : 

Valid Date From : 2020-01-10

Valid Date Until : 2024-05-26

Confirmation Letter No. : CL 098084 0005 Rev. 00

Valid Date From : 2024-05-26

Valid Date Until : 2028-12-31

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Place, Date of Issue :

Shenzhen, Jun.20th, 2024

Signature : 薛秉明

Position: General Manager

Annex I List Of Fitting/Adapters

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
CTA-M01	06941691954156	CTA-M03	06941691959793	CTA-M04	06941691959809
TNC-RP-AA001	06941691954157	EKA-LCA-I	06941691959794	EKA-BS-10	06941691959810
EKA-BG-10	06941691954158	EKA-SEA	06941691959795	EKA-LCA-A	06941691959811
CTA-S05	06941691954159	ELA-PH5-D5	06941691959796	EKA-SEA-A	06941691959812
ELAB-TMX5-PH5-A	06941691954160	ELAB-TMX5-PH5-I	06941691959797	ELAB-TMX5PH-PH5-A	06941691959813
ELAB-TMX5PH-PH5-I	06941691954161	ELA-DG5-D5	06941691959798	ELA-MS-G-BK	06941691959814
ELA-TMX5-CV5-A	06941691954162	ELA-TMX5-CV5-I	06941691959799	ELA-TMX5-MQ5-A	06941691959815
ELA-TMX5-MQ5-I	06941691954163	ELA-TMX5NE-CV5-A	06941691959800	ELA-TMX5NE-CV5-I	06941691959816
ELA-TMX5NE-MQ5-A	06941691954164	ELA-TMX5NE-MQ5-I	06941691959801	ELA-TMX5NE-PH5-A	06941691959817
ELA-TMX5NE-PH5-I	06941691954165	ELA-TMX5-PH5-A	06941691959802	ELA-TMX5-PH5-I	06941691959818
ELA-TMX5PH-CV5-A	06941691954166	ELA-TMX5PH-CV5-I	06941691959803	ELA-TMX5PH-MQ5-A	06941691959819
ELA-TMX5PH-MQ5-I	06941691954167	ELA-TMX5PH-PH5-A	06941691959804	ELA-TMX5PH-PH5-I	06941691959820
TNC-AA003	06941691954168	TNC-NC004	06941691959805	TNC-NC005	06941691959821
TNC-NC006	06941691954169	TNC-NC007	06941691959806	TNC-NC008	06941691959822
TNC-NC009	06941691954170	TNC-NC010	06941691959807	TNC-NC011	06941691959823
TNC-NC012	06941691954171	TNC-NC013	06941691959808	TNC-NC020	06941691959824
TNC-NC021	06941691954172	TNC-NC022	06941691959809	TNC-NC024	06941691959825
TNC-NC025	06941691954173	TNC-NC026	06941691959810	TNC-NC027	06941691959826
TNC-NC028	06941691954174	TNC-NC029	06941691959811	TNC-NC030	06941691959827
TNC-NC040	06941691954175	TNC-NC042	06941691959812	TNC-NC043	06941691959828
TNC-NC044	06941691954176	TNC-NC045	06941691959813	TNC-NC046	06941691959829
TNC-NC047	06941691954177	TNC-NC049	06941691959814	TNC-NC050	06941691959830
TNC-NC051	06941691954178	TNC-NC052	06941691959815	TNC-NIBP-X-001	06941691959831
TNC-SL014	06941691954179	TNC-SL015	06941691959816	TNC-SL017	06941691959832
TNC-SL031	06941691954180	TNC-SL032	06941691959817	TNC-SL037	06941691959833
TNC-SL048	06941691954181	EKA-BW-10	06941691959818	EKA-LCP-A	06941691959834
EKA-LCP-I	06941691954182	EKA-SEP	06941691959819	EKA-US-14-I	06941691959835
EKA-US-14-A	06941691954183	EKA-US-12-I	06941691959820	EKA-US-12-A	06941691959836
EKA-UG-12-I	06941691954184	EKA-UG-12-A	06941691959821	EKA-UB-12-I	06941691959837
EKA-UB-12-A	06941691954185	EKA-UB-14-I	06941691959822	EKA-UB-14-A	06941691959838
EKA-UW-14-I	06941691954186	EKA-UW-14-A	06941691959823	EKA-BW-14	06941691959839

EKA-UA-10-I	06941691954187	EKA-UA-10-A	06941691959824	EKA-US-10-I	06941691959840
EKA-US-10-A	06941691954188	EKA-UG-14-I	06941691959825	EKA-UG-14-A	06941691959841
EKA-UB-10-I	06941691954189	EKA-UB-10-A	06941691959826	EKA-UG-10-I	06941691959842
EKA-UG-10-A	06941691954190	EKA-NW-10	06941691959827	EKA-BW-10	06941691959843
EKA-NA-10	06941691954191	EKA-BA-10	06941691959828	EKA-NF-10	06941691959844
EKA-BF-10	06941691954192	EKA-NS-10	06941691959829	EKA-BS-10	06941691959845
EKA-NG-10	06941691954193	EKA-BG-10	06941691959830	CTA-M04	06941691959846
CTA-M03	06941691954194	CTA-S04	06941691959831	CTA-S03	06941691959847
CTA-S02	06941691954195	CTA-S01	06941691959832	CTA-M02	06941691959848
TNC-AA002	06941691954196	TNC-SL016	06941691959833	TNC-PH-ST001	06941691959849
ELAB-TMX5NE-PH5	06941691954197	ELAB-TMX5NE-PH5-A	06941691959834	ELA-DG5-D5-A	06941691959850
ELA-DG5-D5-I	06941691954198	ELAG-TMX5NE-PH5-A	06941691959835	ELA-MQ5-D5-A	06941691959851
ELA-MQ5-D5-I	06941691954199	ELA-MR5-D5-A	06941691959836	ELA-MR5-D5-I	06941691959852
ELA-NKA5-D5-A	06941691954200	ELA-NKA5-D5-I	06941691959837	ELA-PH5-D5-A	06941691959853
ELA-PH5-D5-I	06941691954201	EKA-B-G-10	06941691946175	EKA-UW-10-I	06941691963592
EKA-BG-3-A	06941691964056	EKA-B-S-10	06941691946182	EKA-VC-10	06941691955450
EKA-UBG-10-A	06941691964711	EKA-N-S-10	06941691946205	EKA-UW-10-A	06941691963585
EKA-UBG-10-I	06941691964728	EKA-LCA-GR4	06941691964841	ELA-SM5-PH5	06941691966524
ELA-NKA5-SL5	06941691966418	ELA-TMX5-PH5	06941691942559	ELA-SM5-SL5	06941691966531
ELA-MQ5-NKA5	06941691966425	ELA-TMX5-MQ5	06941691942566	ELAB-TMX5-PH5	06941691966913
ELA-MQ5-PH5	06941691966432	ELA-TMX5-CV5	06941691942573	ELAB-TMX5PH-PH5	06941691967170
ELA-MQ5-SL5	06941691966449	ELA-TMX5PH-PH5	06941691942580	ELA-TMX5NE-CV5	06941691954781
ELA-MQ5-SM5	06941691966456	ELA-TPH5-CV5	06941691954521	ELA-MQ5-CV5	06941691960577
ELA-NKA5-PH5	06941691966463	ELA-TMX5NE-PH5	06941691954743	ELA-SL5-PH5	06941691966500
ELA-NKA5-SM5	06941691966470	ELA-TMX5PH-MQ5	06941691954750	ELA-SM5-NKA5	06941691966517
ELA-SL5-SM5	06941691966487	ELA-TMX5NE-MQ5	06941691954767	ELA-TMX5PH-CV5	06941691954774
ELA-SL5-NKA5	06941691966494	BPC48	06941691973799	BPC12	06941691973782
BPC38	06941691975229	BPC11	06941691975212	BPC10	06941691975205
BPC10-D	06941691978954	BPC24	06941691978671	BPC25	06941691978688
BPC26	06941691978695	BPC28	06941691978701	BPC37	06941691978664
BPC39	06941691978718	BPC42	06941691978725	BPC38-45	06941691980827
EKA-B-S-A-10	06941691969877	EKA-N-G-A-10	06941691969884		