

EU DECLARATION OF CONFORMITY

Document No. : DOC-009-01

Rev: A8

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

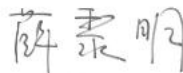
EN ISO 15223-1: 2021

Directive 2011/65/EU Annex II (EU) 2015/863

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

CE mark : 

Place, Date of Issue :

Signature : 

Shenzhen, Aug . 27th, 2024

Position: General Manager

Annex I List Of Fitting/Adapters

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
CTA-M01	06941691954156	CTA-M03	06941691959793	ELAB-TMX5PH-PH5-A	06941691979586
CTA-S05	06941691979364	EKA-LCA-I	06941691946120	ELA-MS-G-BK	06941691979371
ELAB-TMX5-PH5-A	06941691979562	EKA-SEA	06941691946151	ELA-TMX5-MQ5-A	06941691979401
ELAB-TMX5PH-PH5-I	06941691979593	ELA-PH5-D5	06941691946199	ELA-TMX5NE-CV5-I	06941691979555
ELA-TMX5-CV5-A	06941691979425	ELAB-TMX5-PH5-I	06941691979579	ELA-TMX5NE-PH5-A	06941691979463
ELA-TMX5-MQ5-I	06941691979418	ELA-DG5-D5	06941691975724	ELA-TMX5-PH5-I	06941691979395
ELA-TMX5NE-MQ5-A	06941691979500	ELA-TMX5-CV5-I	06941691979432	ELA-TMX5PH-MQ5-A	06941691979487
ELA-TMX5NE-PH5-I	06941691979470	ELA-TMX5NE-CV5-A	06941691979548	ELA-TMX5PH-PH5-I	06941691979456
ELA-TMX5PH-CV5-A	06941691979524	ELA-TMX5NE-MQ5-I	06941691979517	TNC-NC005	06941691979005
ELA-TMX5PH-MQ5-I	06941691979494	ELA-TMX5-PH5-A	06941691979388	TNC-NC008	06941691979036
TNC-AA003	06941691979357	ELA-TMX5PH-CV5-I	06941691979531	TNC-NC011	06941691979067
TNC-NC006	06941691979012	ELA-TMX5PH-PH5-A	06941691979449	TNC-NC020	06941691979104
TNC-NC009	06941691979043	TNC-NC004	06941691978992	TNC-NC024	06941691979135
TNC-NC012	06941691979074	TNC-NC007	06941691979029	TNC-NC027	06941691979166
TNC-NC021	06941691979111	TNC-NC010	06941691979050	TNC-NC030	06941691979197
TNC-NC025	06941691979142	TNC-NC013	06941691979081	TNC-NC043	06941691979258
TNC-NC028	06941691979173	TNC-NC022	06941691979128	TNC-NC046	06941691979289
TNC-NC040	06941691979234	TNC-NC026	06941691979159	TNC-NC050	06941691979326
TNC-NC044	06941691979265	TNC-NC029	06941691979180	TNC-NIBP-X-001	06941691978985
TNC-NC047	06941691979296	TNC-NC042	06941691979241	TNC-SL017	06941691977483
TNC-NC051	06941691979333	TNC-NC045	06941691979272	TNC-SL037	06941691979227
TNC-SL014	06941691977476	TNC-NC049	06941691979319	EKA-LCP-A	06941691946137
TNC-SL031	06941691979203	TNC-NC052	06941691979340	EKA-US-14-I	06941691961680
TNC-SL048	06941691979302	TNC-SL015	06941691979098	EKA-US-12-A	06941691961659
EKA-LCP-I	06941691946144	TNC-SL032	06941691979210	EKA-UB-12-I	06941691961628
EKA-US-14-A	06941691961673	EKA-SEP	06941691946168	EKA-UB-14-A	06941691954026
EKA-UG-12-I	06941691961642	EKA-US-12-I	06941691961666	EKA-BW-14	06941691946779
EKA-UB-12-A	06941691961611	EKA-UG-12-A	06941691961635	EKA-US-10-I	06941691946380
EKA-UW-14-I	06941691946793	EKA-UB-14-I	06941691954033	EKA-UG-14-A	06941691946359
EKA-UA-10-I	06941691946762	EKA-UW-14-A	06941691946786	EKA-UG-10-I	06941691946328
EKA-US-10-A	06941691946373	EKA-UA-10-A	06941691946755	EKA-BW-10	06941691946298
EKA-UB-10-I	06941691946342	EKA-UG-14-I	06941691946366	EKA-NF-10	06941691946267
EKA-UG-10-A	06941691946311	EKA-UB-10-A	06941691946335	EKA-BS-10	06941691946236
EKA-NA-10	06941691946281	EKA-NW-10	06941691946304	CTA-M04	06941691959809
EKA-BF-10	06941691946250	EKA-BA-10	06941691946274	CTA-S03	06941691954194
EKA-NG-10	06941691946229	EKA-NS-10	06941691946243	CTA-M02	06941691954163
CTA-S02	06941691954187	EKA-BG-10	06941691946212	TNC-PH-ST001	06941691980643
TNC-AA002	06941691980247	CTA-S04	06941691954200	ELA-DG5-D5-A	06941691980322
ELAB-TMX5NE-PH5	06941691979685	CTA-S01	06941691954170	ELA-MQ5-D5-A	06941691980308
ELA-DG5-D5-I	06941691980377	TNC-SL016	06941691980254	ELA-MR5-D5-I	06941691980384

ELA-MQ5-D5-I	06941691980353	ELAB-TMX5NE-PH5-A	06941691979692	ELA-PH5-D5-A	06941691980315
ELA-NKA5-D5-A	06941691980346	ELAG-TMX5NE-PH5-A	06941691980223	EKA-UW-10-I	06941691963592
ELA-PH5-D5-I	06941691980360	ELA-MR5-D5-A	06941691980339	EKA-VC-10	06941691955450
EKA-BG-3-A	06941691964056	ELA-NKA5-D5-I	06941691980391	EKA-UW-10-A	06941691963585
EKA-UBG-10-A	06941691964711	EKA-B-G-10	06941691946175	ELA-SM5-PH5	06941691966524
EKA-UBG-10-I	06941691964728	EKA-B-S-10	06941691946182	ELA-SM5-SL5	06941691966531
ELA-NKA5-SL5	06941691966418	EKA-N-S-10	06941691946205	ELAB-TMX5-PH5	06941691966913
ELA-MQ5-NKA5	06941691966425	EKA-LCA-GR4	06941691964841	ELAB-TMX5PH-PH5	06941691967170
ELA-MQ5-PH5	06941691966432	ELA-TMX5-PH5	06941691942559	ELA-TMX5NE-CV5	06941691954781
ELA-MQ5-SL5	06941691966449	ELA-TMX5-MQ5	06941691942566	ELA-MQ5-CV5	06941691960577
ELA-MQ5-SM5	06941691966456	ELA-TMX5-CV5	06941691942573	ELA-SL5-PH5	06941691966500
ELA-NKA5-PH5	06941691966463	ELA-TMX5PH-PH5	06941691942580	ELA-SM5-NKA5	06941691966517
ELA-NKA5-SM5	06941691966470	ELA-TPH5-CV5	06941691954521	ELA-TMX5PH-CV5	06941691954774
ELA-SL5-SM5	06941691966487	ELA-TMX5NE-PH5	06941691954743	BPC12	06941691973782
ELA-SL5-NKA5	06941691966494	ELA-TMX5PH-MQ5	06941691954750	BPC10	06941691975205
BPC38	06941691975229	ELA-TMX5NE-MQ5	06941691954767	BPC25	06941691978688
BPC10-D	06941691978954	BPC48	06941691973799	BPC37	06941691978664
BPC26	06941691978695	BPC11	06941691975212	BPC38-45	06941691980827
BPC39	06941691978718	BPC24	06941691978671	TNC-RP-DA002	06941691969334
EKA-B-S-A-10	06941691969877	BPC28	06941691978701	EKA-LCA-A	06941691946113
TNC-RP-AA001	06941691969327	BPC42	06941691978725	EKA-N-G-A-10	06941691969884
EKA-SEA-A	06941691978732				