

EU DECLARATION OF CONFORMITY

Document No. : DOC-009-01

Rev: B0

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

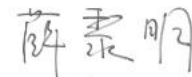
Directive 2011/65/EU Annex II (EU) 2015/863

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

CE mark : 

Place, Date of Issue :

Signature :



Shenzhen, Jan. 15th, 2025

Position: General Manager

Annex I List Of Fitting/Adapters

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
BPC01P-45	06941691981404	EKA-B-G-I-10	06941691914235	EKA-UA-10-A	06941691946755
BPC38-45	06941691980827	EKA-N-G-A-10	06941691969884	EKA-US-10-I	06941691946380
BPC42	06941691978725	EKA-B-S-A-10	06941691969877	EKA-US-10-A	06941691946373
BPC39	06941691978718	EKA-N-G-I-10	06941691914891	EKA-UG-14-I	06941691946366
BPC37	06941691978664	EKA-UBG-10-I	06941691964728	EKA-UG-14-A	06941691946359
BPC28	06941691978701	EKA-UBG-10-A	06941691964711	EKA-UB-10-I	06941691946342
BPC26	06941691978695	EKA-BG-3-A	06941691964056	EKA-UB-10-A	06941691946335
BPC25	06941691978688	EKA-UW-10-I	06941691963592	EKA-UG-10-I	06941691946328
BPC24	06941691978671	EKA-UW-10-A	06941691963585	EKA-UG-10-A	06941691946311
BPC10-D	06941691978954	EKA-US-14-I	06941691961680	EKA-NW-10	06941691946304
BPC10	06941691975205	EKA-US-14-A	06941691961673	EKA-BW-10	06941691946298
BPC11	06941691975212	EKA-US-12-I	06941691961666	EKA-NA-10	06941691946281
BPC38	06941691975229	EKA-US-12-A	06941691961659	EKA-BA-10	06941691946274
BPC12	06941691973782	EKA-UG-12-I	06941691961642	EKA-NF-10	06941691946267
BPC48	06941691973799	EKA-UG-12-A	06941691961635	EKA-BF-10	06941691946250
CTA-S05	06941691979364	EKA-UB-12-I	06941691961628	EKA-NS-10	06941691946243
CTA-M04	06941691959809	EKA-UB-12-A	06941691961611	EKA-BS-10	06941691946236
CTA-M03	06941691959793	EKA-VC-10	06941691955450	EKA-NG-10	06941691946229
CTA-S04	06941691954200	EKA-UB-14-I	06941691954033	EKA-BG-10	06941691946212
CTA-S03	06941691954194	EKA-UB-14-A	06941691954026	EKA-N-S-10	06941691946205

CTA-S02	06941691954187	EKA-UW-14-I	06941691946793	EKA-B-S-10	06941691946182
CTA-S01	06941691954170	EKA-UW-14-A	06941691946786	EKA-B-G-10	06941691946175
CTA-M02	06941691954163	EKA-BW-14	06941691946779	EKA-N-S-I-10	06941691913832
CTA-M01	06941691954156	EKA-UA-10-I	06941691946762	EKA-B-G-A-10	06941691913948
TNC-PH-ST001	06941691980643	ELA-PH5-D5-I	06941691980360	ELA-TMX5PH-PH5-A	06941691979449
EKA-B-S-I-10	06941691912798	ELA-PH5-D5-A	06941691980315	ELA-TMX5PH-MQ5-I	06941691979494
CA-PH-RP-03	06941691966852	ELA-NKA5-D5-I	06941691980391	ELA-TMX5PH-MQ5-A	06941691979487
EKA-N-S-A-10	06941691913733	ELA-NKA5-D5-A	06941691980346	ELA-TMX5PH-CV5-I	06941691979531
ELAB-TMX5NE-PH5-A	06941691979692	ELA-MR5-D5-I	06941691980384	ELA-TMX5PH-CV5-A	06941691979524
ELAB-TMX5NE-PH5	06941691979685	ELA-MR5-D5-A	06941691980339	ELA-TMX5-PH5-I	06941691979395
ELAB-TMX5PH-PH5-I	06941691979593	ELA-MQ5-D5-I	06941691980353	ELA-TMX5-PH5-A	06941691979388
ELAB-TMX5PH-PH5-A	06941691979586	ELA-MQ5-D5-A	06941691980308	ELA-TMX5NE-PH5-I	06941691979470
ELAB-TMX5-PH5-I	06941691979579	ELA-DG5-D5-I	06941691980377	ELA-TMX5NE-PH5-A	06941691979463
ELAB-TMX5-PH5-A	06941691979562	ELA-DG5-D5-A	06941691980322	ELA-TMX5NE-MQ5-I	06941691979517
ELAB-TMX5PH-PH5	06941691967170	ELA-TMX5PH-PH5-I	06941691979456	ELA-TMX5NE-MQ5-A	06941691979500
ELAB-TMX5-PH5	06941691966913	ELA-SL5-NKA5	06941691966494	ELA-TMX5NE-CV5-I	06941691979555
ELA-TMX5NE-CV5-A	06941691979548	ELA-SL5-SM5	06941691966487	ELA-TMX5PH-MQ5	06941691954750
ELA-TMX5-MQ5-I	06941691979418	ELA-NKA5-SM5	06941691966470	ELA-TMX5NE-PH5	06941691954743
ELA-TMX5-MQ5-A	06941691979401	ELA-NKA5-PH5	06941691966463	ELA-TPH5-CV5	06941691954521
ELA-TMX5-CV5-I	06941691979432	ELA-MQ5-SM5	06941691966456	ELA-TMX5PH-PH5	06941691942580
ELA-TMX5-CV5-A	06941691979425	ELA-MQ5-SL5	06941691966449	ELA-TMX5-CV5	06941691942573
ELA-DG5-D5	06941691975724	ELA-MQ5-PH5	06941691966432	ELA-TMX5-MQ5	06941691942566

ELA-PH5-D5	06941691946199	ELA-MQ5-NKA5	06941691966425	ELA-TMX5-PH5	06941691942559
ELA-SM5-SL5	06941691966531	ELA-NKA5-SL5	06941691966418	TNC-NC010	06941691979050
ELA-SM5-PH5	06941691966524	ELA-MQ5-CV5	06941691960577	TNC-NC009	06941691979043
ELA-SM5-NKA5	06941691966517	ELA-TMX5NE-CV5	06941691954781	TNC-NC008	06941691979036
ELA-SL5-PH5	06941691966500	ELA-TMX5PH-CV5	06941691954774	TNC-NC007	06941691979029
TNC-CO2-SY02	06941691982258	ELA-TMX5NE-MQ5	06941691954767	TNC-NC006	06941691979012
TNC-RP-AA001	06941691969327	TNC-NC044	06941691979265	TNC-NC005	06941691979005
TNC-SL016	06941691980254	TNC-NC043	06941691979258	TNC-NC004	06941691978992
TNC-PH-P001	06941691980438	TNC-NC042	06941691979241	TNC-AA003	06941691979357
TNC-ETCO2-MR-001	06941691980575	TNC-NC040	06941691979234	TNC-RP-DA002	06941691969334
TNC-AA002	06941691980247	TNC-NC030	06941691979197	TNC-NC046	06941691979289
TNC-SL048	06941691979302	TNC-NC029	06941691979180	TNC-NC045	06941691979272
TNC-SL037	06941691979227	TNC-NC028	06941691979173	TNC-NC013	06941691979081
TNC-SL032	06941691979210	TNC-NC027	06941691979166	TNC-NC012	06941691979074
TNC-SL031	06941691979203	TNC-NC026	06941691979159	TNC-NC011	06941691979067
TNC-SL017	06941691977483	TNC-NC025	06941691979142	TNC-NC049	06941691979319
TNC-SL015	06941691979098	TNC-NC024	06941691979135	TNC-NC047	06941691979296
TNC-SL014	06941691977476	TNC-NC022	06941691979128	TNC-NC050	06941691979326
TNC-NC052	06941691979340	TNC-NC021	06941691979111	TNC-NC020	06941691979104
TNC-NC051	06941691979333	TNC-NC033	06941691982548	TNC-NC034	06941691982555
TNC-NC035	06941691982562	TNC-NC036	06941691982579	TNC-SL039	06941691977469

ELAG-TMX5NE-PH5-A	06941691980223	TNC-CO2-SY03	06941691911739		
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