

EU DECLARATION OF CONFORMITY

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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

Hejreskovvej 8, 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: 2016

DIRECTIVE 2011/65/EU

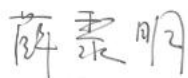
Notified Body : TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany

CE mark : 

Valid Date From : 2020-01-10

Valid Date Until : 2024-05-26

Place, Date of Issue :

Signature : 

Shenzhen, May.20th, 2024

Position: General Manager

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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	06941691969327	EKA-LCA-I	06941691946120	EKA-BS-10	06941691946236
EKA-BG-10	06941691946212	EKA-SEA	06941691946151	EKA-LCA-A	06941691946113
CTA-S05	06941691979364	ELA-PH5-D5	06941691975700	EKA-SEA-A	06941691978732
ELAB-TMX5-PH5-A	06941691979562	ELAB-TMX5-PH5-I	06941691979579	ELAB-TMX5PH-PH5-A	06941691979586
ELAB-TMX5PH-PH5-I	06941691979593	ELA-DG5-D5	06941691975724	ELA-MS-G-BK	06941691979371
ELA-TMX5-CV5-A	06941691979425	ELA-TMX5-CV5-I	06941691979432	ELA-TMX5-MQ5-A	06941691979401
ELA-TMX5-MQ5-I	06941691979418	ELA-TMX5NE-CV5-A	06941691979548	ELA-TMX5NE-CV5-I	06941691979555
ELA-TMX5NE-MQ5-A	06941691979500	ELA-TMX5NE-MQ5-I	06941691979517	ELA-TMX5NE-PH5-A	06941691979463
ELA-TMX5NE-PH5-I	06941691979470	ELA-TMX5-PH5-A	06941691979388	ELA-TMX5-PH5-I	06941691979395
ELA-TMX5PH-CV5-A	06941691979524	ELA-TMX5PH-CV5-I	06941691979531	ELA-TMX5PH-MQ5-A	06941691979487
ELA-TMX5PH-MQ5-I	06941691979494	ELA-TMX5PH-PH5-A	06941691979449	ELA-TMX5PH-PH5-I	06941691979456
TNC-AA003	06941691979357	TNC-NC004	06941691978992	TNC-NC005	06941691979005
TNC-NC006	06941691979012	TNC-NC007	06941691979029	TNC-NC008	06941691979036
TNC-NC009	06941691979043	TNC-NC010	06941691979050	TNC-NC011	06941691979067
TNC-NC012	06941691979074	TNC-NC013	06941691979081	TNC-NC020	06941691979104
TNC-NC021	06941691979111	TNC-NC022	06941691979128	TNC-NC024	06941691979135
TNC-NC025	06941691979142	TNC-NC026	06941691979159	TNC-NC027	06941691979166
TNC-NC028	06941691979173	TNC-NC029	06941691979180	TNC-NC030	06941691979197

TNC-NC040	06941691979234	TNC-NC042	06941691979241	TNC-NC043	06941691979258
TNC-NC044	06941691979265	TNC-NC045	06941691979272	TNC-NC046	06941691979289
TNC-NC047	06941691979296	TNC-NC049	06941691979319	TNC-NC050	06941691979326
TNC-NC051	06941691979333	TNC-NC052	06941691979340	TNC-NIBP-X-001	06941691978985
TNC-SL014	06941691977476	TNC-SL015	06941691979098	TNC-SL017	06941691977483
TNC-SL031	06941691979203	TNC-SL032	06941691979210	TNC-SL037	06941691979227
TNC-SL048	06941691979302	EKA-BW-10	06941691946298	EKA-LCP-A	06941691946137
EKA-LCP-I	06941691946144	EKA-SEP	06941691946168	EKA-US-14-I	06941691961680
EKA-US-14-A	06941691961673	EKA-US-12-I	06941691961666	EKA-US-12-A	06941691961659
EKA-UG-12-I	06941691961642	EKA-UG-12-A	06941691961635	EKA-UB-12-I	06941691961628
EKA-UB-12-A	06941691961611	EKA-UB-14-I	06941691954033	EKA-UB-14-A	06941691954026
EKA-UW-14-I	06941691946793	EKA-UW-14-A	06941691946786	EKA-BW-14	06941691946779
EKA-UA-10-I	06941691946762	EKA-UA-10-A	06941691946755	EKA-US-10-I	06941691946380
EKA-US-10-A	06941691946373	EKA-UG-14-I	06941691946366	EKA-UG-14-A	06941691946359
EKA-UB-10-I	06941691946342	EKA-UB-10-A	06941691946335	EKA-UG-10-I	06941691946328
EKA-UG-10-A	06941691946311	EKA-NW-10	06941691946304	EKA-BW-10	06941691946298
EKA-NA-10	06941691946281	EKA-BA-10	06941691946274	EKA-NF-10	06941691946267
EKA-BF-10	06941691946250	EKA-NS-10	06941691946243	EKA-BS-10	06941691946236
EKA-NG-10	06941691946229	EKA-BG-10	06941691946212	CTA-M04	06941691959809
CTA-M03	06941691959793	CTA-S04	06941691954200	CTA-S03	06941691954200
CTA-S02	06941691954187	CTA-S01	06941691977452	CTA-M02	06941691954163

TNC-AA002	06941691980247	TNC-SL016	06941691980254	TNC-PH-ST001	06941691980643
ELAB-TMX5NE-PH5	06941691979685	ELAB-TMX5NE-PH5-A	06941691979692	ELA-DG5-D5-A	06941691980322
ELA-DG5-D5-I	06941691980377	ELAG-TMX5NE-PH5-A	06941691980223	ELA-MQ5-D5-A	06941691980308
ELA-MQ5-D5-I	06941691980353	ELA-MR5-D5-A	06941691980339	ELA-MR5-D5-I	06941691980384
ELA-NKA5-D5-A	06941691980346	ELA-NKA5-D5-I	06941691980391	ELA-PH5-D5-A	06941691980315
ELA-PH5-D5-I	06941691980360				