

EU DECLARATION OF CONFORMITY

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Manufacturer: Orantech Inc.

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SRN : CN-MF-000013859

EC- Representative: Medten EU ApS

Oldenvej 33, 3490 Kvistgård, Denmark

SRN : DK-AR-000034434

Product Name : Patient Cable(TEMP Adapter Cables)

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH05QX

UMDNS Code : 16316

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

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Place, Date of Issue :

Signature : 薛素明

Shenzhen, Jun. 21st, 2024

Position: General Manager

Annex I List Of TEMP Adapter Cables

Model	UDI-DI	Model	UDI-DI
TA-PH-AD03	06970706367179	TA-MRA-YSI30	06970706367353
TA-MQ-AD03	06970706367186	TA-MRB-YSI30	06970706367360
TA-DG-AD03	06970706367193	TA-BLT-YSI30	06970706367377
TA-SL-AD03	06970706367209	TA-SW-YSI30	06970706367384
TA-MRA-AD03	06970706367216	TA-IFN-YSI30	06970706367391
TA-MRB-AD03	06970706367223	TA-Y400S-YSI30	06941691954545
TA-BLT-AD03	06970706367230	TA-Y400-PM30	06970706367407
TA-SW-AD03	06970706367247	TA-PH-PM30	06970706367414
TA-IFN-AD03	06970706367254	TA-MQ-PM30	06970706367421
TA-MRA-AD25	06941691962373	TA-DG-PM30	06970706367438
TA-MQ-2AD03	06970706367261	TA-SL-PM30	06970706367445
TA-MQ700-2AD03	06970706367278	TA-MRA-PM30	06970706367452
TA-SL-2AD03	06970706367285	TA-MRB-PM30	06970706367469
TA-Y400-YSI30	06970706367308	TA-BLT-PM30	06970706367476
TA-PH-YSI30	06970706367315	TA-SW-PM30	06970706367483
TA-MQ-YSI30	06970706367322	TA-IFN-PM30	06970706367490
TA-DG-YSI30	06970706367339	TA-Y400S-PM30	06941691962779
TA-SL-YSI30	06970706367346	TAF-FP02-045	06941691968979
TAF-FP04-10	06941691974895	TA-FDA-2AD40	06941691974949
TA-FDA-2AD05	06941691974970	TAF-FP01-09	06941691968962
TA-MQ-2YSI36	06941691977148	TA-MQ-2YSI12	06941691977155
TA-MQ-2PM30	06941691977162	TA-ST-YSI05	06941691965374
TAF-FP03-045	06941691968986	TAF-FP04-09	06941691969006
TAF-FP05-11	06941691968993	TAT-PH01-MD15	06941691971023

TAT-Y400S-MD15	06941691971030	TAT-Y700S-MD15	06941691971047
TAT-PH02-SC03	06941691971054	TA-NK-2AD03	06970706367292
TA-P63SB-YSI30	06941691947066	TA-PH-AD18	06941691963578

