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EU DECLARATION OF CONFORMITY

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Manufacturer: Orantech Inc.
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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 Annex II (EU) 2015/863

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

CE mark : CE

Place, Date of Issue : **Signature :**

Shenzhen, Jan. 9th , 2025 **Position:** General Manager

Annex I List Of TEMP Adapter Cables

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
TA-MQ-AD05	06941691981886	TA-P63SB-YSI30	06941691947066	TA-DG-YSI30	06970706367339
TA-AT-AT03	06941691981480	TA-IFN-PM30	06970706367490	TA-MQ-YSI30	06970706367322
TA-MQ-2YSI12	06941691977155	TA-SW-PM30	06970706367483	TA-PH-YSI30	06970706367315
TA-AT01-AT03	06941691980957	TA-BLT-PM30	06970706367476	TA-Y400-YSI30	06970706367308
TAT-PH02-SC03	06941691971054	TA-MRB-PM30	06970706367469	TA-NK-2AD03	06970706367292
TAT-Y700S-MD15	06941691971047	TA-MRA-PM30	06970706367452	TA-SL-2AD03	06970706367285
TAT-Y400S-MD15	06941691971030	TA-SL-PM30	06970706367445	TA-MQ700-2AD03	06970706367278
TAT-PH01-MD15	06941691971023	TA-DG-PM30	06970706367438	TA-MQ-2AD03	06970706367261
TA-MQ-2PM30	06941691977162	TA-MQ-PM30	06970706367421	TA-IFN-AD03	06970706367254
TA-MQ-2YSI36	06941691977148	TA-PH-PM30	06970706367414	TA-SW-AD03	06970706367247
TA-FDA-2AD05	06941691974970	TA-Y400-PM30	06970706367407	TA-BLT-AD03	06970706367230
TA-FDA-2AD40	06941691974949	TA-IFN-YSI30	06970706367391	TA-MRB-AD03	06970706367223
TA-ST-YSI05	06941691965374	TA-SW-YSI30	06970706367384	TA-MRA-AD03	06970706367216
TA-Y400S-PM30	06941691962779	TA-BLT-YSI30	06970706367377	TA-SL-AD03	06970706367209
TA-PH-AD18	06941691963578	TA-MRB-YSI30	06970706367360	TA-DG-AD03	06970706367193
TA-MRA-AD25	06941691962373	TA-MRA-YSI30	06970706367353	TA-MQ-AD03	06970706367186
TA-Y400S-YSI30	06941691954545	TA-SL-YSI30	06970706367346	TA-PH-AD03	06970706367179
TA-T35-T15	06941691918431	TA-PH-MD15	06941691919025		