

## ***EU DECLARATION OF CONFORMITY***

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**Manufacturer:** Orantech Inc.

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New District, Shenzhen, China.518106  
SRN : CN-MF-000013859

**EC- Representative:** Cables and Sensors B.V.

Zekeringstraat 21B , 1014 BM Amsterdam, Netherlands  
SRN : NL-AR-000012545

**Product Name :** Patient Cable(TEMP Adapter Cables)

**Product Models :** Please see the Annex I

**Basic UDI - DI:** 69416919ORANTECH05QX

**UMDNS Code :** 16316

**Classification(MDR Annex VIII) :** Class I, Rule1

**Conformity Assessment Route :** Annex II +III in 2017/745/EEC MDR

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, the provisions of council MDR 2017/745/EEC of 26 May, 2020 concerning medical devices. All supporting documentations are retained under the premises of the manufacturer. We, the manufacturer, are exclusively responsible for doc.

**Standard Applied :**

|                      |                          |
|----------------------|--------------------------|
| EN ISO 14971:2019    | IEC 60601-1:2005/A1:2012 |
| IEC 60601-1-2:2014   | EN ISO 15223-1:2020      |
| EN 1041:2008         | ANSI/AAMI EC53 : 2013    |
| EN ISO 10993-1:2018  | EN ISO 10993-5:2009      |
| EN ISO 10993-10:2010 |                          |


**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, July. 1<sup>st</sup>, 2021

**Position:** General Manager

**Orantech Inc.**

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**Annex I List Of TEMP Adapter Cables**

| Model          | UDI-DI        | Model          | UDI-DI        |
|----------------|---------------|----------------|---------------|
| TA-PH-AD03     | 6970706367179 | TA-MRA-YSI30   | 6970706367353 |
| TA-MQ-AD03     | 6970706367186 | TA-MRB-YSI30   | 6970706367360 |
| TA-DG-AD03     | 6970706367193 | TA-BLT-YSI30   | 6970706367377 |
| TA-SL-AD03     | 6970706367209 | TA-SW-YSI30    | 6970706367384 |
| TA-MRA-AD03    | 6970706367216 | TA-IFN-YSI30   | 6970706367391 |
| TA-MRB-AD03    | 6970706367223 | TA-Y400S-YSI30 | 6941691954545 |
| TA-BLT-AD03    | 6970706367230 | TA-Y400-PM30   | 6970706367407 |
| TA-SW-AD03     | 6970706367247 | TA-PH-PM30     | 6970706367414 |
| TA-IFN-AD03    | 6970706367254 | TA-MQ-PM30     | 6970706367421 |
| TA-MRA-AD25    | 6941691962373 | TA-DG-PM30     | 6970706367438 |
| TA-MQ-2AD03    | 6970706367261 | TA-SL-PM30     | 6970706367445 |
| TA-MQ700-2AD03 | 6970706367278 | TA-MRA-PM30    | 6970706367452 |
| TA-SL-2AD03    | 6970706367285 | TA-MRB-PM30    | 6970706367469 |
| TA-Y400-YSI30  | 6970706367308 | TA-BLT-PM30    | 6970706367476 |
| TA-PH-YSI30    | 6970706367315 | TA-SW-PM30     | 6970706367483 |
| TA-MQ-YSI30    | 6970706367322 | TA-IFN-PM30    | 6970706367490 |
| TA-DG-YSI30    | 6970706367339 | TA-Y400S-PM30  | 6941691962779 |
| TA-SL-YSI30    | 6970706367346 |                |               |