

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

**Document No. :** DOC-009-02

**Rev:** A3

**Manufacturer:** Orantech Inc.

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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 :** Bandage

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

**Basic UDI -DI:** 69416919ORANTECH22QX

**UMDNS Code :** 10274

**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

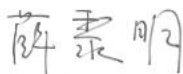
DIRECTIVE 2011/65/EU

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

**CE mark :** 

**Place, Date of Issue :**

Shenzhen, Jun. 25<sup>th</sup>, 2024

**Signature :** 

**Position:** General Manager

**Annex I List of Bandage**

| Model       | UDI-DI         | Model    | UDI-DI         | Model       | UDI-DI         |
|-------------|----------------|----------|----------------|-------------|----------------|
| M07-B001    | 06941691977193 | M07-B002 | 06941691977209 | M07-B002-08 | 06941691977216 |
| M07-B001-08 | 06941691977223 | M07-B003 | 06941691977230 | M07-B004    | 06941691977247 |
| M07-B003-08 | 06941691977254 | M07-B006 | 06941691977261 | M07-B006-08 | 06941691977278 |