

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

**Document No. :** DOC-008-02

**Rev:** B1

**Manufacturer:** Orantech Inc.

Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community, GongMing, Guangming  
New District, Shenzhen, China.518106

SRN : CN-MF-000013859

**EU- Representative:** Medten EU ApS

Oldenvej 33, 3490 Kvistgård, Denmark

SRN : DK-AR-000034434

**Product Name :** Tourniquet Hoses

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

**Basic UDI - DI:** 69416919ORANTECH18R8

**UMDNS Code :** 11073

**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+A1:2025

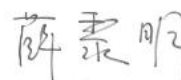
Directive 2011/65/EU Annex II (EU) 2015/863

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

**CE mark :** 

**Place, Date of Issue :**

**Signature :**



Shenzhen, Sep. 28<sup>th</sup>, 2025

**Position:** General Manager

### Annex I List of Tourniquet Hoses

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
TH-BD40-1212-4848	06941691975663	TH-BS45-48-12	06941691973638	TH-DD40-4949-4848	06941691965510
TH-RD40-1212-4848	06941691975656	TH-CS40-48-12	06941691973652	TH-RD40-4949-4848	06941691965503
TH-Y-48-1212	06941691975557	TH-RS30-48-12	06941691973560	TH-BD40-4949-4848	06941691965497
TH-BKS40-48-12	06941691974581	TH-RS45-48-12	06941691973621	CH-BS30-49-48	06941691966715
TH-SS40-48-12-CBK	06941691974598	TH-RS60-48-12	06941691973577	TH-BS40-49-48	06941691966999
TH-BCD40-4848-1212	06941691973669	TH-BS30-51-52	06941691968368	TH-RS40-49-48	06941691966982
TH-BKS30-48-04M	06941691973607	TH-SS40-12-48	06941691967002	TH-BS30-48-12	06941691973584
TH-BKS60-48-04M	06941691973614	TH-RS40-12-03M	06941691985747	TH-BS40-12-03M	06941691985754
TH-SS40-12-03M	06941691985761				