

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: 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

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

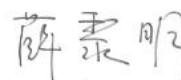
Notified Body : TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany

CE mark : 

Place, Date of Issue :

Shenzhen, Sept. 25th, 2024

Signature :



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				