

EU DECLARATION OF CONFORMITY

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Manufacturer: Orantech Inc.

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SRN : CN-MF-000013859

EU- Representative: Medten EU ApS

Oldenvej 33, 3490 Kvistgård, Denmark

SRN : DK-AR-000034434

Product Name : DRAIN, TEE (WATER TRAP)

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH23QZ

UMDNS Code : 18059

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, May. 12th, 2025

Position: General Manager

Annex I List Of DRAIN, TEE

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
TNC-MR-WT054	06941691980568	TNC-ETCO2-MR-001	06941691980575	TNC-WT002	06941691977285
TNC-ED-WT001	06941691982678				