

EU DECLARATION OF CONFORMITY

Document No. : DOC-009-03

Rev: A2

Manufacturer: Orantech Inc.

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SRN : CN-MF-000013859

EC- 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

DIRECTIVE 2011/65/EU

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

CE mark : 

Valid Date From : 2020-01-10

Valid Date Until : 2024-05-26

Confirmation Letter No. : CL 098084 0005 Rev. 00

Valid Date From : 2024-05-26

Valid Date Until : 2028-12-31

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Place, Date of Issue :

Shenzhen, Jun 21st, 2024

Signature : 薛素明

Position: General Manager

Annex I List Of DRAIN, TEE

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