

EU DECLARATION OF CONFORMITY

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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 : Tapes, Adhesive

Product Models: Please see the Annex I

Basic UDI - DI: 69416919ORANTECH15R2

UMDNS Code : 10030

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 : 

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Place, Date of Issue :

Shenzhen, Jun. 21st, 2024

Signature : 薛素明

Position: General Manager

Annex I List of Tapes, Adhesive

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
DPT-A	06941691959915	DPT-A-M	06941691966333	DPT-P	06941691966340
DPT-P-M	06941691966357	DPT-N	06941691966364	DPT-N-M	06941691966296