Orantech
The difference you can sense

EU DECLARATION OF CONFORMITY

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EC- Representative: Medten EU ApS
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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 Annex II (EU) 2015/863

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

CE mark： CE

Place, Date of Issue：

Shenzhen, Sept. 24th, 2024

Signature：

Position: General Manager

Annex I List of Tapes, Adhesive

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