

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 : Bandage

Product Models : Please see the Annex I

Basic UDI -DI: 69416919ORANTECH22QX

UMDNS Code : 10274

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

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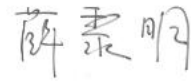
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Place, Date of Issue :

Shenzhen, Jun. 21st, 2024

Signature :



Position: General Manager

Annex I List of Bandage

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
M07-B001	06941691977193	M07-B002	06941691977209	M07-B002-08	06941691977216
M07-B001-08	06941691977223	M07-B003	06941691977230	M07-B004	06941691977247
M07-B003-08	06941691977254	M07-B006	06941691977261	M07-B006-08	06941691977278