EU DECLARATION OF CONFORMITY

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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 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. 25th, 2024

Signature :

Position: General Manager

Annex I List of Bandage

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