

EU DECLARATION OF CONFORMITY

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Manufacturer: Orantech Inc.

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SRN : CN-MF-000013859

EC- Representative: Medten EU ApS

Hejreskovvej 8, 3490 Kvistgård, Denmark
SRN : DK-AR-000034434

Product Name : ETCO2 Sensor

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH12QU

UMDNS Code : 17224

Classification - Annex IX : Class IIb , Rule10

Conformity Assessment Route : Annex II

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 transposition national law, the provisions of Council Directive 93/42/EEC Concerning Medical Devices. 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: 2016
ISO 80601-2-55:2018	EN62366-1:2015
IEC 60601-1:2005/A1:2012	IEC 60601-1-2: 2014
DIRECTIVE 2011/65/EU	

Notified Body : TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany

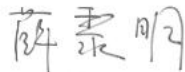
CE mark: 

EC Certificate No. : G1 098084 0003 Rev. 01

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Valid Date Until : 2024-05-26

Place, Date of Issue :

Signature : 

Shenzhen, Apr. 12th, 2024

Position: General Manager

Orantech Inc.

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Annex I List of ETCO2 Sensor

Model	UDI-DI	Model	UDI-DI
CTM-RP01	06970706360668	CTS-RP01	06970706360712
CTM-PH01	06970706360675	CTS-PH01	06970706360729
CTM-PS01	06970706360682	CTS-PS01	06970706360736
CTM-ZL01	06970706360699	CTS-ZL01	06970706360743
CTM-MR01	06970706360705	CTS-MR01	06970706360750
CTM-NK01	06941691962878	CTM-HT01	06941691962601
CTA-M01	06941691954156		