

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 : 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: 2021

ISO 80601-2-55:2011

EN62366-1:2015

Directive 2011/65/EU Annex II (EU) 2015/863 IEC 60601-1-2: 2014

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

CE mark: 

EC Certificate No. : G1 098084 0003 Rev. 01

Valid Date From : 2020-01-10

Valid Date Until : 2024-05-26

Confirmation Letter No. : CL 098084 0005 Rev. 00

Valid Date From : 2024-05-26

Valid Date Until : 2028-12-31

Place, Date of Issue :

Shenzhen, Aug. 27th, 2024

Signature : 薛永明

Position: General Manager

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
CTS-HT01	06941691962618		