

## ***EU DECLARATION OF CONFORMITY***

**Document No. :** DOC-007-01

**Rev:** B3

**Manufacturer:** Orantech Inc.

Zone#A, 4F, 1<sup>st</sup> Bld, 7th Industrial Zone, Yulv Community, GongMing, Guangming  
New District, Shenzhen, China.518106  
SRN : CN-MF-000013859

**EU- 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+A1:2025

ISO 80601-2-55:2011

EN 62366-1:2015

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

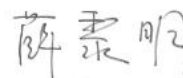
**Valid Date From :** 2024-05-26

**Valid Date Until :** 2028-12-31

Place, Date of Issue :

Shenzhen, Sep.28<sup>th</sup>, 2025

Signature :



Position: General Manager

**Annex I List of ETCO2 Sensor**

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
CTM-NK01	06941691962878	CTM-PS01	06970706360682	CTS-HT01	06941691962618
CTM-HT01	06941691962601	CTM-PH01	06970706360675	CTS-MR01	06970706360750
CTM-MR01	06970706360705	CTM-RP01	06970706360668	CTS-ZL01	06970706360743
CTM-ZL01	06970706360699	CTS-PH01	06970706360729	CTS-PS01	06970706360736
CTS-RP01	06970706360712	CTM-ED01	06941691985334	CTM-BL01	06941691985341
CTM-CM01	06941691985358	CTM-HWT01	06941691985372	CTM-MD01	06941691985396
CTM-CN01	06941691985365	CTM-UC01	06941691985389	CTM-BN01	06941691985402
CTM-RP02	06941691986652				