

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: Cables and Sensors B.V.

Zekeringstraat 21B , 1014 BM Amsterdam, Netherlands
SRN : NL-AR-000012545

Product Name : ETCO2 Sensor

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH12QU

UMDNS Code : 17224

Classification : Class IIb , Rule10 (Annex VIII of MDR 2017/745/EEC)

Conformity Assessment Route : According to Annex IX chapter I and III of MDR 2017/745/EEC

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, the provisions of council MDR 2017/745/EEC of 26 May, 2020 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 ISO 14971:2019 | IEC 60601-1-2:2014 |
| IEC 60601-1:2005/A1:2012 | EN 1041:2008 |
| EN ISO 15223-1:2020 | ISO 80601-2-55:2018 (E) |
| IEC 62366 : 2015 | |

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

CE mark: 

EC Certificate No. : G1 098084 0003 Rev. 01

Valid Date From : 2020-07-10

Valid Date Until : 2024-07-10

Place, Date of Issue :

Shenzhen, July. 1st, 2021

Signature : 
Position: General Manager

Annex I List of ETCO2 Sensor

| Model | UDI-DI | Model | UDI-DI |
|--------------|---------------|--------------|---------------|
| CTM-RP01 | 6970706360668 | CTS-RP01 | 6970706360712 |
| CTM-PH01 | 6970706360675 | CTS-PH01 | 6970706360729 |
| CTM-PS01 | 6970706360682 | CTS-PS01 | 6970706360736 |
| CTM-ZL01 | 6970706360699 | CTS-ZL01 | 6970706360743 |
| CTM-MR01 | 6970706360705 | CTS-MR01 | 6970706360750 |
| CTM-NK01 | 6941691962878 | | |