

EU DECLARATION OF CONFORMITY

Document No. : DOC-007-01

Rev: A1

Manufacturer: Orantech Inc.

Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community, GongMing, Guangming
New District, Shenzhen, China.518106

EC- Representative: Cables and Sensors B.V.

Zekeringstraat 21B
1014 BM Amsterdam, Netherlands

Product Name : ETCO2 Sensor

Product Models: CTM-RP01, CTM-PH01, CTM-PS01, CTM-ZL01, CTM-MR01, CTS-RP01, CTS-PH01,
CTS-PS01, CTS-ZL01, CTS-MR01

UMDNS Code : 17224

Classification : Class IIb, Rule10 (According to Annex IX of directive 93/42/EEC)

Conformity Assessment Route : Annex II without 4 of directive 93/42/EEC

We, Orantech Inc., herewith declare under our sole responsibility that the stated medical devices meet the transposition into national law, the provisions of council directive 93/42/EEC of 14 June, 1993 concerning medical devices; including, on March 21, 2010, the amendments by council directive 2007/47/EEC. All supporting documents are retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for doc.

Standard Applied :

EN ISO 14971:2012	EN ISO 14155:2011
IEC 60601-1:2005/A1:2012	IEC 60601-1-2:2014
EN ISO 15223-1:2016	EN 1041:2008
EN62366 : 2015	ISO 80601-2-55:2018 (E)

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 : 2018-07-10

Valid Date Until : 2022-09-03

Place, Date of Issue :

Shenzhen, July. 10, 2018

Signature :

Position: General Manager

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