

EU DECLARATION OF CONFORMITY

Document No. : DOC-006-02

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 : TOCO Fetal transducer

Product Models : FTC-PH01,FTC-GE01, FTC-GE02, FTC-AL01,FTC-SC01

UMDNS Code : 14119

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

Conformity Assessment Route : Annex II excluding 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	EN ISO 10993-1:2018
EN ISO 10993-5:2009	EN ISO 10993-10:2010
IEC60601-2-37:2007+AMD1:2015	

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 : 2020-01-10

Valid Date Until : 2024-05-26

Place, Date of Issue :

Shenzhen, Jan. 10, 2020

Signature :

Position: General Manager

Orantech Inc.

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