

EU DECLARATION OF CONFORMITY

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Manufacturer: Orantech Inc.

Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community, GongMing, Guangming
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 : TOCO Fetal transducer

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH11QS

UMDNS Code : 14119

Classification - Annex IX : Class IIa , 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

IEC 60601-1:2005/A1:2012

ISO 10993-5:2009

ISO 10993-10:2010

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

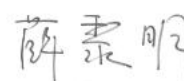
Confirmation Letter No. : CL 098084 0005 Rev. 00

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Place, Date of Issue :

Signature :



Orantech Inc.

T +86-755 2369 9939 **F** +86-755 2324 3594 **E** info@orantech.cn **W** www.orantech.com

Shenzhen, Dec. 9th, 2024

Position: General Manager

Annex I List of TOCO Fetal transducer

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
FTC-BL01	06941691973287	FTC-CM05	06941691974567	FTC-SL02	06970706360620
FTC-GD05	06941691973270	FTC-GE02S	06941691973737	FTC-SL01	06970706360613
FTC-BC01	06941691973263	FTC-SU01	06941691965848	FTC-SC02	06970706360606
FTC-BC02	06941691973256	FTC-NM01	06941691964735	FTC-ED01	06970706360590
FTC-BA01	06941691973249	FTC-ED02	06941691963073	FTC-SC01	06970706360583
FTC-LK01	06941691973232	FTC-BT01	06941691955559	FTC-AL01	06970706360576
FTC-JP01	06941691973225	FTC-BN02	06941691955542	FTC-GE02	06970706360569
FTC-GD03	06941691973218	FTC-BN01	06941691955535	FTC-GE01	06970706360552
FTC-GD01	06941691973201	FTC-NT01	06941691955528	FTC-PH01	06970706360545
FTC-CM03	06941691973195	FTC-SL03	06970706360637	FTC-CM01	06941691973188
FTC-SC01-20	06941691977698				