

EU DECLARATION OF CONFORMITY

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Manufacturer: Orantech Inc.

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SRN : CN-MF-000013859

EC- Representative: Medten EU ApS

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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 60601-2-37:2007

EN ISO 10993-5:2009

EN ISO 10993-10:2010

EN62366-1:2015

DIRECTIVE 2011/65/EU ANNEX II (EU) 2015/863

IEC 60601-1-2: 2014

IEC 60601-1:2005/A1:2012

IEC60601-2-37:2007+AMD1:2015

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 :

Signature : 薛素明

Shenzhen, Aug. 27th, 2024

Position: General Manager

Annex I List of TOCO Fetal transducer

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