

EU DECLARATION OF CONFORMITY

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Manufacturer: Orantech Inc.

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SRN : CN-MF-000013859

EC- Representative: Medten EU ApS

Oldenvej 33, 3490 Kvistgård, Denmark

SRN : DK-AR-000034434

Product Name : Ultrasound Fetal transducer

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH10QQ

UMDNS Code : 14121

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

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

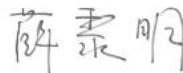
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Valid Date From : 2024-05-26

Valid Date Until : 2028-12-31

Place, Date of Issue :

Signature : 

Shenzhen, Jun.25th, 2024

Position: General Manager

Annex I List of Ultrasound Fetal Transducer

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
FUS-PH01	06970706360385	FUS-SC03	06970706360484	FUS-NM01	06941691964742
FUS-PH02	06970706360392	FUS-SL03	06970706360491	FUS-GE02S	06941691973720
FUS-GE01	06970706360408	FUS-AL02	06970706360507	FUS-ED01	06970706360477
FUS-GE02	06970706360415	FUS-AL03	06970706360514	FUS-BT01	06941691955511
FUS-SL01	06970706360422	FUS-SC04	06970706360521	FUS-SC02	06970706360460
FUS-SL02	06970706360439	FUS-ED02	06970706360538	FUS-BN02	06941691955504
FUS-AL01	06970706360446	FUS-NT01	06941691955481	FUS-BN01	06941691955498
FUS-SC01	06970706360453	FUSTC-CM06	06941691974574	FUS-CM05	06941691974550
FUS-CM01	06941691973003	FUS-CM02	06941691973010	FUS-CM03	06941691973027
FUS-CM04	06941691973034	FUS-ED03	06941691973041	FUS-GD01	06941691973058
FUS-GD02	06941691973065	FUS-GD04	06941691973072	FUS-JP01	06941691973089
FUS-JP02	06941691973096	FUS-LK01	06941691973102	FUS-TY01	06941691973119
FUS-BA01	06941691973126	FUS-BC02	06941691973133	FUS-BC01	06941691973140
FUS-GM01	06941691973157	FUS-SC05	06941691973164	FUS-BL01	06941691973171
FUS-SU01	06941691965855	FUS-GD05	06941691966661	FUSTC-CT01	06941691973294
FUSTC-GD01	06941691973300	FUSTC-GD02	06941691973317	FUSTC-GD03	06941691973324
FUSTC-JP01	06941691973331	FUSTC-LK01	06941691973348	FUSTC-TY01	06941691973355
FUSTC-BA02	06941691973362	FUSTC-CT02	06941691973379	FUS-NT02	06941691955481