

EU DECLARATION OF CONFORMITY

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Manufacturer: Orantech Inc.

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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 : 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	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
IEC 60601-1:2005/A1:2012	

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

Orantech Inc.

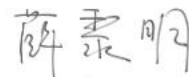
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Valid Date From : 2024-05-26

Valid Date Until : 2028-12-31

Place, Date of Issue :

Signature :



Shenzhen, Dec. 9th, 2024

Position: General Manager

Annex I List of Ultrasound Fetal Transducer

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
FUS-GE03	06941691981268	FUS-JP02	06941691973096	FUS-BN01	06941691955498
FUS-CM06	06941691981060	FUS-JP01	06941691973089	FUS-NT02	06941691955481
FUSTC-CT02	06941691973379	FUS-GD04	06941691973072	FUS-ED02	06970706360538
FUSTC-BA02	06941691973362	FUS-GD02	06941691973065	FUS-SC04	06970706360521
FUSTC-TY01	06941691973355	FUS-GD01	06941691973058	FUS-AL03	06970706360514
FUSTC-LK01	06941691973348	FUS-ED03	06941691973041	FUS-AL02	06970706360507
FUSTC-JP01	06941691973331	FUS-CM04	06941691973034	FUS-SL03	06970706360491
FUSTC-GD03	06941691973324	FUS-CM03	06941691973027	FUS-SC03	06970706360484
FUSTC-GD02	06941691973317	FUS-CM02	06941691973010	FUS-ED01	06970706360477
FUSTC-GD01	06941691973300	FUS-CM01	06941691973003	FUS-SC02	06970706360460
FUSTC-CT01	06941691973294	FUS-CM05	06941691974550	FUS-SC01	06970706360453
FUS-BL01	06941691973171	FUSTC-CM06	06941691974574	FUS-AL01	06970706360446
FUS-SC05	06941691973164	FUS-GE02S	06941691973720	FUS-SL02	06970706360439
FUS-GM01	06941691973157	FUS-GD05	06941691966661	FUS-SL01	06970706360422
FUS-BC01	06941691973140	FUS-SU01	06941691965855	FUS-GE02	06970706360415
FUS-BC02	06941691973133	FUS-NT01	06941691965237	FUS-GE01	06970706360408

FUS-BA01	06941691973126	FUS-NM01	06941691964742	FUS-PH02	06970706360392
FUS-TY01	06941691973119	FUS-BT01	06941691955511	FUS-PH01	06970706360385
FUS-LK01	06941691973102	FUS-BN02	06941691955504	FUS-SC04-20	06941691982647