

## ***EU DECLARATION OF CONFORMITY***

**Document No. :** DOC-006-01

**Rev:** A3

**Manufacturer:** Orantech Inc.

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District, Shenzhen, China.518106  
SRN : CN-MF-000013859

**EC- Representative:** Cables and Sensors B.V.

Zekeringstraat 21B , 1014 BM Amsterdam, Netherlands  
SRN : NL-AR-000012545

**Product Name :** Ultrasound Fetal transducer

**Product Models :** Please see the Annex I

**Basic UDI - DI:** 69416919ORANTECH10QQ

**UMDNS Code :** 14121

**Classification :** Class IIa , Rule10 ( Annex VIII of MDR 2017/745/EEC )

**Conformity Assessment Route :** According to Annex IX chapter I and III of MDR 2017/745/EEC

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 Medical Device Regulation, the provisions of council MDR 2017/745/EEC of 26 May, 2020 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 ISO 14971:2019	EN ISO 10993-10:2010
IEC 60601-1:2005/A1:2012	IEC 60601-1-2:2014
EN ISO 15223-1:2020	EN 1041:2008
IEC 62366 : 2015	IEC60601-2-37:2007+AMD1:2015
EN ISO 10993-1:2018	EN ISO 10993-5:2009

**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 :** 2020-07-10

**Valid Date Until :** 2024-07-10

**Place, Date of Issue :**

**Signature :** 

Shenzhen, July. 1<sup>st</sup>, 2021

**Position:** General Manager

**Annex I List of Ultrasound Fetal Transducer**

Model	UDI-DI	Model	UDI-DI
FUS-PH01	6970706360385	FUS-SC03	6970706360484
FUS-PH02	6970706360392	FUS-SL03	6970706360491
FUS-GE01	6970706360408	FUS-AL02	6970706360507
FUS-GE02	6970706360415	FUS-AL03	6970706360514
FUS-SL01	6970706360422	FUS-SC04	6970706360521
FUS-SL02	6970706360439	FUS-ED02	6970706360538
FUS-AL01	6970706360446	FUS-NT01	6941691955481
FUS-SC01	6970706360453	FUS-BN01	6941691955498
FUS-SC02	6970706360460	FUS-BN02	6941691955504
FUS-ED01	6970706360477	FUS-BT01	6941691955511