Orantech
"The difference you can sense"

EU DECLARATION OF CONFORMITY

Document No.：DOC-006-01 **Rev:** A1

Manufacturer: Orantech Inc.
Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community, GongMing, Guangming New District, Shenzhen, China.518106

EC- Representative: Cables and Sensors B.V.
Zekeringstraat 21B
1014 BM Amsterdam, Netherlands

Product Name：Ultrasound Fetal transducer

Product Models： FUS-PH01, FUS-PH02, FUS-GE01, FUS-GE02, FUS-SL01, FUS-SL02, FUS-AL01, FUS-SC01, FUS-SC02

UMDNS Code：14121

Classification：Class IIa, Rule10 (According to Annex IX of directive 93/42/EEC)

Conformity Assessment Route：Annex II excluding 4 of directive 93/42/EEC

We, Orantech Inc., herewith declare under our sole responsibility that the stated medical devices meet the transposition into national law, the provisions of council directive 93/42/EEC of 14 June, 1993 concerning medical devices; including, on March 21, 2010, the amendments by council directive 2007/47/EEC. All supporting documents are retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for doc.

Standard Applied：

EN ISO 14971:2012	EN ISO 14155:2011
IEC 60601-1:2005/A1:2012	IEC 60601-1-2:2014
EN ISO 15223-1:2016	EN 1041:2008
EN 62366:2015	IEC60601-2-37:2007+AMD1:2015
EN ISO 10993-1:2018	EN ISO 10993-5:2009
EN ISO 10993-10:2010	

Notified Body：TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany

CE mark: CE 0123

EC Certificate No.：G1 098084 0003 Rev. 01

Valid Date From： 2020-01-10 **Valid Date Until：** 2024-05-26

Place, Date of Issue：

Shenzhen, Jan. 10, 2020

Signature： Hsin.xiong

Position: General Manager

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