

EU DECLARATION OF CONFORMITY

Document No. : DOC-001-02

Rev: A0

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 : Patient Cables (DECG Legplate Adapter Cables)

Product Models : Please see the Annex I

UMDNS Code : 16316

Classification : Class I, Rule 1 (According to Annex IX of directive 93/42/EEC)


Conformity Assessment Route : Annex VII 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	IEC 60601-1:2005/A1:2012
IEC 60601-1-2:2014	EN ISO 15223-1:2016
EN 1041:2008	ANSI/AAMI EC53 : 2013
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 : 

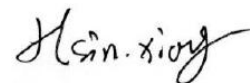
Valid Date From : 2018-07-10

Valid Date Until : 2022-09-03

Place, Date of Issue :

Shenzhen, May. 20, 2020

Signature :



Position: General Manager

Orantech Inc.

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Annex I List Of DECG Legplate Adapter Cables

FDELA-PH01-SPE	FDELA-PH01-SGE	FDELA-PH01-SKE
FDELA-PH03-SPE	FDELA-PH03-SGE	FDELA-PH03-SKE
FDELA-GE01-SPE	FDELA-GE01-SGE	FDELA-GE01-SKE
FDELA-GE02-SPE	FDELA-GE02-SGE	FDELA-GE02-SKE
FDELA-HL01-SPE	FDELA-HL01-SGE	FDELA-HL01-SKE
FDELA-HL02-SPE	FDELA-HL02-SGE	FDELA-HL02-SKE