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EU DECLARATION OF CONFORMITY

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Manufacturer: Orantech Inc.
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SRN：CN-MF-000013859

EC- Representative: Cables and Sensors B.V.
Zekeringstraat 21B，1014 BM Amsterdam, Netherlands
SRN：NL-AR-000012545

Product Name： Patient Cables (DECG Legplate Adapter Cables)

Product Models： Please see the Annex I

Basic UDI - DI: 69416919ORANTECH02QR

UMDNS Code：16316

Classification(MDR Annex VIII)：Class I, Rule1

Conformity Assessment Route：Annex II +III in 2017/745/EEC MDR

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	IEC 60601-1:2005/A1:2012
IEC 60601-1-2:2014	EN ISO 15223-1:2020
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： CE

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

Place, Date of Issue： **Signature：**

Shenzhen, July. 1st, 2021 **Position:** General Manager

Annex I List Of DECG Legplate Adapter Cables

Model	UDI-DI	Model	UDI-DI
FDELA-PH01-SPE	6941691955290	FDELA-GE02-SKE	6941691955351
FDELA-GE01-SPE	6941691955306	FDELA-PH01-SKE	6941691955368
FDELA-GE02-SPE	6941691955313	FDELA-PH01-SKE06	6941691955375
FDELA-HL01-SPE	6941691955320	FDELA-PH03-SKE	6941691955382
FDELA-HL02-SPE	6941691959373	FDELA-HL01-SKE	6941691955399
FDELA-GE01-SKE	6941691955344	FDELA-HL02-SKE	6941691957799