

EU DECLARATION OF CONFORMITY

Document No. : DOC-001-02

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Manufacturer: Orantech Inc.

Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community, GongMing, Guangming
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 : Patient Cables (DECG Legplate Adapter Cables)

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH02QR

UMDNS Code : 16316

Classification - Annex VIII : Class I, Rule 1

Conformity Assessment Route : Annex IX

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 2017/745. 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

Directive 2011/65/EU Annex II (EU) 2015/863

Notified Body : TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany

CE mark : 

Place, Date of Issue :

Signature : 

Shenzhen, Aug. 27th, 2024

Position: General Manager

Annex I List Of DECG Legplate Adapter Cables

Model	UDI-DI	Model	UDI-DI
FDELA-PH01-SPE	06941691955290	FDELA-ED01-SGE	06941691981152
FDELA-GE01-SPE	06941691955306	FDELA-GE02-SKE	06941691955351
FDELA-GE02-SPE	06941691955313	FDELA-PH01-SKE	06941691955368
FDELA-HL01-SPE	06941691955320	FDELA-PH01-SKE06	06941691955375
FDELA-HL02-SPE	06941691959373	FDELA-PH03-SKE	06941691955382
FDELA-GE01-SKE	06941691955344	FDELA-HL01-SKE	06941691955399
FDELA-PH01-SGE	06941691955337	FDELA-HL02-SKE	06941691957799
FDELA-GE02-SGE	06941691965039	FDELA-PH01-SPE07	06941691968382
FDELA-NT01-SNE	06941691974901	FDELA-NT01-SPE	06941691974161
FDELA-NT01-SGE	06941691974185	FDELA-NT01-SKE	06941691974178
FDELA-HL02-SGE	06941691973416	FDELA-HL01-SGE	06941691973409
FDELA-PH01-SGE07	06941691970231	FDELA-GE01-SGE	06941691964834
FDELA-SL01-SKE	06941691981121	FDELA-SL01-SPE	06941691981107
FDELA-ED01-SPE	06941691981114	FDELA-SL01-SGE	06941691981145
FDELA-ED01-SKE	06941691981138		