

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

**Document No. :** DOC-001-02

**Rev:** B4

**Manufacturer:** Orantech Inc.

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SRN : CN-MF-000013859

**EU- 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+A1:2025

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, May. 12<sup>th</sup>, 2025

**Position:** General Manager

**Annex I List Of DECG Legplate Adapter Cables**

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