

EU DECLARATION OF CONFORMITY

Document No. : DOC-001-09

Rev: A6

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 Cable

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH24R3

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

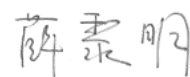
Directive 2011/65/EU Annex II (EU) 2015/863

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

CE mark : 

Place, Date of Issue :

Shenzhen, Dec. 2nd, 2024

Signature : 

Position: General Manager

Annex I List of Patient Cable

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
BISA-NK01-30	06941691981091	EKT-PH-RJ45-20	06941691979708	IPC-AL02	06941691980230
BISA-3F01-30	06941691973492	EKT-DG-DG-50	06941691980551	IPC-ST01	06941691959076
BISA-FD01-30	06941691975649	EKT-DG-DG-30	06941691980544	IPC-BT01	06941691959069
BISA-SLG01-30	06941691974253	EKT-DG-DG-03	06941691980537	FM-007	06941691977377
BISA-SY01-30	06941691974031	EKT-GE-MAC-25	06941691974086	FM-06	06941691973393
BISA-PH01-30	06941691966869	EKT-PH-AD25	06941691966708	FM-05	06941691973386
BISA-GE01-30	06941691964988	EKT-PH-PIM	06941691966227	FM-003	06941691959045
BISA-AP01-30	06941691959137	EKT-GE-MAX1	06941691945260	FM-002	06970706360651
BISA-MR01-30	06941691959120	EKT-GE-MAXP-S	06941691945253	FM-001	06970706360644
BISB-AP02-13	06941691966081	EKT-GE-MAXP	06941691945246	EKT-GE-CAM14-S	06941691945215
BISB-AP01-13	06941691964971	EKT-GE-AM4-S	06941691945239	EKT-GE-AM4	06941691945222
EKT-GE-CAM14	06941691945208	BISB-RD01-09	06941691908548		