

EU DECLARATION OF CONFORMITY

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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 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

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

CE mark : 

Valid Date From : 2020-01-10

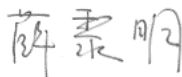
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Place, Date of Issue :

Signature : 

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Shenzhen, Jun.21st, 2024

Position: General Manager

Annex I List of Patient Cable

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
BISA-MR01-30	06941691959120	BISA-AP01-30	06941691959137	BISB-AP01-13	06941691964971
BISA-3F01-30	06941691973492	BISA-PH01-30	06941691966869	BISA-SY01-30	06941691974031
BISA-SLG01-30	06941691974253	BISA-FD01-30	06941691975649	BISA-GE01-30	06941691964988
BISB-AP02-13	06941691966081	EKT-DG-DG-03	06941691980537	EKT-DG-DG-30	06941691980544
EKT-DG-DG-50	06941691980551	EKT-PH-RJ45-20	06941691979708	IPC-AL02	06941691980230
IPC-BT01	06941691959069	IPC-ST01	06941691959076	FM-003	06941691959045
FM-002	06970706360651	FM-001	06970706360644	DCC-AD01-30	06941691954231
DCC-PH01-09	06941691954224	DCC-FN01-30	06941691954217	NC-002	06941691962885
BISB-AP01-11	06941691964971	BISB-AP02-11	06941691966081	EKT-PH-AD25	06941691966708
IPC-AL01	06941691970156	TNC-IPP-AL-002	06941691970002	FM-05	06941691973386
FM-06	06941691973393	FM-007	06941691977377	NC-001	06941691959052