

EU DECLARATION OF CONFORMITY

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Manufacturer: Orantech Inc.

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SRN : CN-MF-000013859

EC- Representative: Medten EU ApS

Oldenvej 33, 3490 Kvistgård, Denmark

SRN : DK-AR-000034434

Product Name : Patient Cables (Cardiac output cables)

Product Models : Please see the Annex I

Basic UDI - DI: 69416919ORANTECH19RA

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

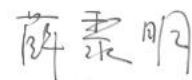
Notified Body : TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany

CE mark : 

Place, Date of Issue :

Shenzhen, Feb. 17th, 2025

Signature :



Position: General Manager

Annex I List Of Patient Cables (Cardiac output cables)

Model	UDI-DI	Model	UDI-DI	Model	UDI-DI
COCA-PH-27	06941691980520	COCA-MQ-36	06941691973683	COCB-PH-48	06941691969976
COCB-DG01-25	06941691971061	COCA-MR01-01	06941691982821	COCA-MR02-01	06941691982838
COCA-MR03-01	06941691982845	COCA-ED01-01	06941691982852	COCA-PH01-01	06941691982869
COCA-SL01-01	06941691982876	COCA-BLT01-01	06941691982883		