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# *EU DECLARATION OF CONFORMITY*

**Document No.：**DOC-001-07 **Rev:** A4

**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

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

**CE mark：** CE

**Place, Date of Issue：**

Shenzhen, Jun 25th, 2024

**Signature：**

**Position:** General Manager

## Annex I List Of Patient Cables (Cardiac output cables)

| Model | UDI-DI | Model | UDI-DI | | |
|---|---|---|---|---|---|
| COCB-DG01-25 | 06941691971061 | COCB-PH-48 | 06941691969976 | COCA-MQ-36 | 06941691973683 |
| COCA-PH-27 | 06941691980520 | | | | |
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