

EU DECLARATION OF CONFORMITY

TO REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5
April 2017 On Medical Devices

Declaration Number:

RDM-CE-03-005 REV: A/0 Date: 2021-6-10

The Manufacturer:

Shenzhen Redy-Med Technology Co., Ltd.

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Product Name:

Temperature Adaptor Cable

The temperature Adaptor Cable is a kind of auxiliary accessory of the temperature probe, which is intended to connect the temperature probe and the monitor equipment together to realize the continuous measurement of human

body temperature.

Sterile/Measurement

/Reusable Surgical

Not applicable

Models:

TA004-A, TA005-A, TA008-A and TA009-A

Classification:

Class I, Rule 13

Conformity Assessment Route:

ANNEX II and III: Tech Documentation and Article 19 DOC

We herewith declare that the above mentioned products(s) meet the transposition into national law and the provisions of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 On Medical Devices. All supporting documentation is retained at the premises of the manufacturer.





Regulatory Compliance:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

Standards Applied:

EN ISO 13485: 2012; EN ISO 14971: 2012; EN 1041:2008+A1:2013; EN ISO 15223-1:2016; EN 60601-1-6:2010+A1:2015; EN 60601-1:2006+A1:2013; EN 60601-1-2:2015;



Start of CE-Marking:

18 February 2020

Place, Date of Issue:

Shenzhen, Jun 10,202

Signature:

Name:

Title:

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General Manager

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