

EU DECLARATION OF CONFORMITY

Doc. No./Rev: Ber-DC-040/A0

No.: BEK-CE-23-005

Manufacturer Guangzhou Berrcom Medical Device Co., Ltd.
No.38 Huanzhen Xi Road, Dagang Town, Nansha, 511470 Guangzhou,
Guangdong, PEOPLE'S REPUBLIC OF CHINA

Single Registration Number (SRN): CN-MF-000013852

Authorized Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537, Hamburger, Germany.

SRN Authorized Representative: DE-AR-000000001

Product Identification

Product/Trade Name: Non-contact Infrared Thermometer
Model: JXB-319

Basic UDI-DI: 69476561JXB-XXX7T

Product Code

GMDN Code: 17888
GMDN Term: Infrared patient thermometer, skin
EMDN Code: V0301010202
EMDN Term: NON-CONTACT DIGITAL THERMOMETERS

Classification

Risk Class: Class IIa
(According to rule 10 of Annex VIII Medical Device Regulation (EU) 2017/745)

Conformity assessment Route: Annex IX chapter I + chapter III of Regulation (EU) 2017/745

We (Guangzhou Berrcom Medical Device Co., Ltd) declare that the above medical device is at our sole responsibility the state medical device Non-contact Infrared Thermometer in conformity with the following legislation(s):

Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices

The conformity of the quality management system according to Annex IX and Article 52 is certified by the following notified body:

TÜV SÜD Product service GmbH
Ridlerstr 65, 80339 München, Germany

The identification number of the notified body for implementation of the procedure set out in Annex IX and Article 52 to the above regulation is: 0123

Certificate number of issued certificate: G10 082883 0017 Rev. 00

Reference to Common Specifications: NA

This declaration of conformity is issued under the sole responsibility of Guangzhou Berrcom Medical Device Co., Ltd.

This declaration supersedes any declaration issued previously for the same product.

Place and date <Guangzhou, China, Jul. 07, 2023>

Signature



Name Zhigang Du

Position Person Responsible for Regulatory Compliance

Signature



Name Zhichao Guo

Position General Manager