

EU DECLARATION OF CONFORMITY

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

No.: BER-CE-NC-028

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, Hamburg, Germany.

SRN Authorized Representative: DE-AR-000000001

Product Identification

Product/Trade Name: Nasal Aspirator
Model: NC006, NC007

Basic UDI-DI: 69476561NCXXX4G

Intended use: The device is intended to remove excess mucus from nasal of children.

Product Code

GMDN Code: 56647
GMDN Term: Nasal aspirator, electric
EMDN Code: R05010301
EMDN Term: SINGLE-CHAMBER MUCOUS MEMBRANE ASPIRATORS

Classification

Risk Class: Class IIa
(According to rule 12 of Annex VIII Medical Device Regulation (EU) 2017/745)

Applied Standards: Refer to Annex 1

Conformity assessment Route: Annex IX Chapters I and 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 Nasal Aspirator 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

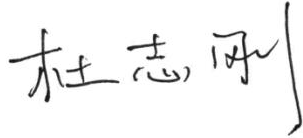
Certificate number of issued certificate: G10 082883 0017 Rev. 00

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, Oct. 25, 2024>

A handwritten signature in black ink, appearing to be the Chinese characters '杜志刚' (Du Zhigang).

Signature

Name Zhigang Du

Position Person Responsible for Regulatory Compliance

A handwritten signature in black ink, appearing to be the Chinese characters '郭志超' (Guo Zhichao).

Signature

Name Zhichao Guo

Position General Manager

Annex 1 Applied Standards

EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971: 2019	Information supplied by the manufacturer of medical devices
EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied — Part 1: General requirements
EN 62304:2006+A1:2015	Medical device software - Software life-cycle processes
EN 60601-1-6:2010+A1+A2:2021	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366-1:2015+A1:2020	Medical devices - Application of usability engineering to medical devices
EN 60601-1:2006/A2:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-11:2015/A1:2021	Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 60601-1-2:2015+A1:2021	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN ISO 10993-1: 2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2023	Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
EN ISO 10993-23:2021	Biological evaluation of medical devices Part 23: Tests for irritation
Regulation (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, amended Directive 2001/83/EC