

**CE Technical File**  
**Technical Documentation of Tape**

File No: HB-CE-Tape

Rev. No: A/0

## ***Declaration of Conformity***

Manufacturer: Zhejiang Hangbiao Medical Products Co., Ltd

118 Trade Road, Meijiang Town, Lanxi City, Jinhua City, Zhejiang  
Province, PEOPLE'S REPUBLIC OF CHINA.

European Caretechion GmbH  
Netherlands Representative: Niederrheinstr. 71, 40474 Duesseldorf, Germany  
E-mail: info@caretechion.de

Product Name: Tape

Models: Various size

UMDNS\_code: 10030

UDI-DI: /

Brand: **HB**



The product concerned has been designed and manufactured under a quality management system according to ANNEX IX of Medical Device REGULATION (EU) 2017/745.

Classification (MDR, Annex VIII ): Class I , rule 1 of MDR Annex VIII

Conformity Assessment Route: Annex II, MDR 2017/745/EU

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

### REGULATIONS

General applicable regulation:

Medical Device Regulation: REGULATION (EU) 2017/745 OF THE EUROPEAN  
PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices

Place, Date of Issue: ZheJiang, 2023-04-15

Signature: \_\_\_\_\_

Name: Gong Chunjuan

Position: Deputy General Manager