



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Name: Shanghai International Holding Corp. GmbH(Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

SRN: DE-AR-000000001

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971:2019/A11:2021, ISO 15223-1:2021+A1:2025,
EN ISO 20417: 2021, EN ISO 10993-1: 2020, EN ISO 10993-5: 2009, EN ISO 10993-10: 2023, EN ISO 13485:2016/A11:2021, ASTM D3330/D3330M-04(2018)

Remark

The declaration of conformity is valid in connection with the release ISO 13485 Certificate by TUV SUD with Notified Body identification no.0123:

ISO 13485:2016 Certificate: Q5 002037 0008 Rev. 06

Expire date of the Certificate:
2028-08-31

Place, Date of Issue: Hubei province, P.R.C, 2025-08-11

Manufacturer

Name: Allmed Medical Products Co., Ltd

ADDRESS: No.18 Qi xing Road, Majiadian Town, 443200Zhijiang City, Hubei province, PEOPLE' S REPUBLIC OF CHINA

SRN: CN-MF-000007970

Product Information

Name:

Non-Sterile Cotton Tape/Sparadrap en cotton

Model: 5360020, 5360050, 5360610,
5360060

EMDN: M0599

Basic UDI:

69415580adhesivetapeVWV

Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare in our own responsibility that the above mentioned products meet the Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

Position: General Manager of Quality

Name: Vince Tian

Place: Zhijiang City

Signature:  ate: 2025-10-23