CE

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
ISO 14971: 2019, ISO 15223-1: 2021
ISO 20417：2021, ISO 10993-1: 2020
ISO 10993-5: 2009, ISO 10993-10: 2021, ISO 10993-11:2017,BS EN 14079:2003, EN ISO 13485:2016

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 Qixing Road, Majiadian Town, 443200Zhijiang City, Hubei province, PEOPLE'S REPUBLIC OF CHINA
SRN: CN-MF-000007970

Product Information

Name:
Non-Sterile Gauze Swabs

Model: please refer to the MDR product list

EMDN: M020105

Basic UDI-DI:
69415580gauzeswabNSIG5

Classification: Class I, According to Rule 4, 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: Zhijang City

Signature: Vince Tian Date: Sep. 01. 2025

Product List

Article number	Description	Size
221110	Non sterile gauze swabs	5×5cm-8ply
225210	Non sterile gauze swabs	10x10-8P
225220	Non sterile gauze swabs	10x10-12P
227210	Non sterile gauze swabs	10x20-8P
227220	Non sterile gauze swabs	10x20-12P