



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 and Annex XI-Part A of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971:2019+A11:2021, EN ISO 13485:2016/A11:2021, EN ISO 15223-1:2021
EN ISO 20417:2021, EN ISO 10993-1:2020,
EN ISO 10993-5: 2009, EN ISO 10993-10:2023, EN ISO 10993-11:2018, BS EN 14079:2003, EN ISO 11737-1:2018/Amd 1:2021

Remark

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

MDR CE Certificate:

G20 002037 0016 Rev.01

Expire date of the Certificate:
2028-07-09

Place, Date of Issue: Hubei province, P.R.C.

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 Lap Sponges (with X-Ray Thread)

Model: please refer to the product list

EMDN: M0201030202

Basic UDI:

69415580lapspongeXNSHJ

Classification: Class IIa, According to Rule 7, 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:  Date: 2025-04-08

Product List

REF	Product Description
761500	Telasorb green 20x30cm 4ply 20thr P40x5 (with x-ray detectable chip)
761501	Telasorb green 45x45cm 4ply 20thr P24x5 (with x-ray detectable chip)
761502	Telasorb green 45x45 cm, 4ply, 20thr, P24x5 (with x-ray detectable chip)
761503	Telasorb green 45x45cm 6ply 20thr P20x5 (with x-ray detectable chip)
761504	Telasorb green 45x45cm 6ply 20thr P20x5 (with x-ray detectable chip)
761505	Telasorb green 50x60cm 4ply 20thr P12x5 (with x-ray detectable chip)
761506	Telasorb green 50x60cm 6ply 20thr P12x5 (with x-ray detectable chip)
761507	Telasorb green 50x60 cm 6ply 20thr P12x5 (with x-ray detectable chip)
761508	Telasorb green 90x8cm 4ply 20thr P30x5 (with x-ray detectable chip)
761509	Telasorb white 20x30 cm 20thr 4ply P40x5 (with x-ray detectable chip)

V. Lian