



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, EN ISO 11737-1:2018/Amd 1:2021, EN ISO 11607-1:2020+A1:2023, EN ISO 11607-2:2020/Amd 1:2023, EN ISO 11135: 2014+A1: 2019, EN ISO 10993-7:2008/A1:2022

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:

G21 002037 0015 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 Qixing Road, Majiadian Town, 443200 Zhijiang City, Hubei province, PEOPLE'S REPUBLIC OF CHINA

SRN: CN-MF-000007970

Product Information

Name: Sterile ABD Pad

Model: please refer to the product list

EMDN: M040201

Basic UDI: 69415580ABDpadT7

Classification: Class Is, 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: Zhijiang City

Signature:  Date: 2025-04-07

Product List

Product Category	Product Code	Specification
Sterile ABD Pads	4137900	10x10cm
	4137910	10x20cm
	4137920	15x20cm
	4137930	15x25cm
	4137940	20x20cm
	4137950	20x25cm
	4137960	20x40cm
	4137810	10x10cm (large size)
	4137830	10x20cm (large size)
	4137820	10x20cm (large size)
	4137800	10x10cm (large size)

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