



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

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

Conformity Assessment

Conformity Assessment Procedure

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

Applicable Standards

EN ISO 14971:2019+A11:2021, EN ISO 13485:2016/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 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.02

Expire date of the Certificate: 2028-07-09

Place, Date of Issue: Hubei province, P.R.C.2025-08-12

Product Information

Name: Sterile ABD Pad

Model: please refer to the MDR 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: Zhijang City

Signature: *Vince Tian* Date: *Oct. 30. 2025*

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Product List for Sterile ABD Pads

Article number	Description	Sterilization
413790	Zetuvit E sterile, 10x10 cm P25	ETO
413791	Zetuvit E sterile, 10x20 cm P25	ETO
413792	Zetuvit E sterile, 15x20 cm P25	ETO
413793	Zetuvit E sterile, 15x25 cm P10	ETO
413794	Zetuvit E sterile, 20x20 cm P15	ETO
413795	Zetuvit E sterile, 20x25 cm P15	ETO
413796	Zetuvit E sterile, 20x40 cm P5	ETO
413781	Zetuvit E sterile, 10x10 cm P25 BE	ETO
413783	Zetuvit E sterile, 10x20 cm P25 BE	ETO
413782	Zetuvit E sterile, 10x20 cm P5 BE	ETO
413780	Zetuvit E sterile, 10x10 cm P10 BE	ETO

Vinre Tian