

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 EN1644-1:1997,
BS EN1644-2:2000, 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 ABD Pad
Model: please refer to the MDR product list
EMDN: M040201
Basic UDI: 69415580ABDpadNSGV
Classification: Class I, According to Rule 4, Annex
VIII, Regulation (EU) 2017/745

Declaration

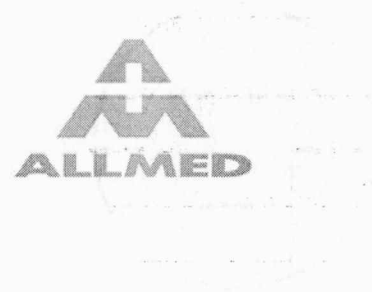
We herewith declare in our own responsibility that
the above mentioned products meet the
Regulation (EU) 2017/745 and, if applicable, with
any other relevant Union legislation that provides for
the issuing of an EU declaration of conformity. All
supporting documentations are retained under the
premises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

Position: General Manager of Quality

Name: Vince Tian Place: Zhijiang City

Signature: *Vince Tian* Date: *Sep. 01. 2025*

No.18 Qixing Road, Majiadian Town, 443200 Zhijiang
City, Hubei Province, P.R.C
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Product List for Non-Sterile ABD Pads

Article number	Description	Sterilization
413890	Zetuvit E unsterile 10x10 cm P50	Non Sterile
413891	Zetuvit E unsterile 10x20 cm P50	Non Sterile
413892	Zetuvit E unsterile 15x20 cm P50	Non Sterile
413894	Zetuvit E unsterile 20x20 cm P50	Non Sterile
413895	Zetuvit E unsterile 20x25 cm P50	Non Sterile
413896	Zetuvit E unsterile 20x40 cm P30	Non Sterile
413897	Zetuvit E unsterile 10x10 cm P50 BE	Non Sterile
413898	Zetuvit E unsterile 10x20 cm P50 BE	Non Sterile
302010	Zetuvit E bulk non sterile 10 x 10 cm	Non Sterile
302011	Zetuvit E bulk non sterile 10 x 20 cm	Non Sterile
302012	Zetuvit E bulk non sterile 15 x 20 cm	Non Sterile

Vince Tica