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

**Applicable Standards**
ISO 14971: 2019, ISO 15223-1: 2021
ISO 20417：2021 EN ISO 10993-1: 2020
ISO 10993-5: 2009, ISO 10993-7:2008/Amd 1:2019,ISO 10993-10: 2021 , ISO 10993-11:2017,BS EN 14079:2003, ISO 11607-1：2019,ISO 11607-2：2019, EN ISO 11135:2014, EN ISO 13485:2016

### Remark

- This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.
- Each kind of medical device to which the declaration of conformity procedures applies, the production quality assurance procedures have also been applied. Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, the classification rules, and these procedures.
- GMDN code: 14077 and term: surgical towel

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.00
Expire date of the Certificate:
Place, Date of Issue: Hubei province, P.R.C,

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

### Manufacturer

**Name:** Allmed Medical Product s 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:**
Sterile OR Towel (with X-Ray Thread)

**Model:**

| Item no. | Short description |
|---|---|
| 28700002XR | OR TOWEL, BLUE, ST, XR, 43X61CM, W/LOOP, 2/PK |
| 28700004XR | OR TOWEL, BLUE, ST, XR, 43X61CM, W/LOOP, 4/PK |

**EMDN:** M02010502

**Basic UDI:** 69415580ORtowelXSJ

**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.

Signature: Date: Apr. 12. 2024
Position: GM of QA&RA Place: Zhijang City