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,

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(without X-Ray Thread)

Model:

Item no.	Short description
28700002CEA	OR TOWEL, BLUE, ST, 43X61CM, 2/PK
28700004CEA	OR TOWEL, BLUE, ST, 43X61CM, 4/PK
28200004CEA	OR TOWEL, GREEN, ST, 43X61CM, 4/PK
28300002CEA	DRAPE TOWEL WHITE 2PK

EMDN: M02010501

Basic UDI: 69415580ORtowel3E

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: Vince Tian Date: Apr. 12. 2024

Position: GM of QA&RA Place: Zhijang City