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,ISO 11607-1：2019, ISO 11607-2：2019, EN ISO 11135:2014, EN ISO 13485:2016

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:

G20 002037 0016 Rev. 00

Expire date of the Certificate: 2028-07-09

Place, Date of Issue: Hubei province, P.R.C,

Manufacturer

Name: Allmed Medical Product s 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:

Sterile Lap Sponges (without x-ray thread)

Model: please refer to the MDR product list

EMDN: M02010301

Basic UDI: 69415580lapspongeKN

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: July.14.2023

Position: GM of QA&RA Place: Zhijang City