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 10993-10: 2021 , 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:
G21 002037 0015 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:
Medical Kits

Model: please refer to the MDR product list

EMDN: T0203

Basic UDI: 69415580medicalkitH8

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.

Signature: Vina Tian Date: July. 14. 2023

Position: GM of QA&RA Place: Zhijang City