DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Cert Gmbh

Harffstr. 47,40591 Düsseldorf, Germany

SRN: DE-AR-000010869

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Intended use

To be used by who suffering shoulder surgery, shoulder dislocation or subluxation.

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y090612-05.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: XIAMEN ORTOCARE SPORTS HEALTH CO., LTD.

Address: Unit 218-2, New Times Building, No.1 Huli Avenue, Xiamen, China (Fujian) Pilot Free Trade Zone

SRN: CN-MF-000034229

Product Information

Name: Shoulder & Arm Brace

Model: AR001, AR002, AR003, AR004, AR005, AR006, AR007, CL001, CL002, CL003, CL003, SH001, SH002, SH003, SH004, SH005

EMDN: Y090612

Basic UDI-DI: 697620010SAB0016A

Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date: 2024.03

Position: GM Place: Fujian/China