



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

Correct postural and medical immobilization Helps immobilize and provide support on wrist area.

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y090612-09.

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: Wrist Brace

Model: WR001, WR002, WR003, WR004, WR005, WR006, WR007, WR008, WR009, WR010, WR011, WR012, WR015, WR016, WR017, WR018, WR019, WR020, WR021, WR022, WR023, WR024, WR025

EMDN: Y090612

Basic UDI-DI: 697620010WristBrace001VJ

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: 2025.04.23

Position: GM

Place: Fujian/China

