



# 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 ankle joint.

## Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-Y090618-04.*

*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:** Ankle Brace  
**Model :** AN001, AN002, AN003, AN004, AN005, AN006, AN007, AN008, AN009, AN010, AN011, AN012, AN013, AFO001, AFO002  
**EMDN:** Y090618  
**Basic UDI-DI:** 697620010AB001ZP  
**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: 2022.04.03

Position: GM  Place: Fujian, China