



# 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

PROTECTS FINGERTIP AND NAIL BED  
INJURIES. PROTECTS AGAINST  
Mallet finger as well

## Remark

*The declaration of conformity is valid in connection  
with the release technical document CE/MDR-  
Y061299-01.*

*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:** FINGER SPLINT  
**Model:** FS001, FS002, FS003, FS004, FS005, FS006  
**EMDN:** Y090699  
**Basic UDI-DI:** 697620010FS0019P  
**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

