



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

**SUNGO Europe B.V.**  
**Olympisch Stadion 24, 1076DE**  
**Amsterdam, Netherlands**  
**SRN: NL-AR-000000247**

## Conformity Assessment

### Conformity Assessment Procedure

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

### Applicable Standards

EN ISO 14971: 2019  
EN ISO 15223-1: 2016  
EN 1041:2008+A1:2013  
ISO 10993-1: 2018  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013

### Remark

*The declaration of conformity is valid in connection with the release technical document CE-FC-001.*

*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:** Forlong Medical Co., Ltd  
**Address:** No. 33 Zhihui Road Huishan District Wuxi  
China

## Product Information

**Name:** Plaster of paris bandage  
**Model:** Length:2.7M,3M,3.6M,4M,4.6M  
Width:5CM,7.5CM,10CM,15CM,20CM  
Special specifications according to customer needs  
**Basic UDI-DI:** 20958913686406ZT  
**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:

Position: GM

Date:

2020.02.01

Place: Wuxi China

