



# 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

## Manufacturer

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

## 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

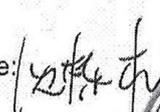
*The declaration of conformity is valid in connection with the release technical document CE-FC-002.*  
*All the supporting documentation is retained at the premises of the manufacturer.*  
*The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.*

## Product Information

**Name:** Dental cotton roll  
**Model:** 8\*30mm/8\*38mm/8\*480mm/8\*800mm/  
 10\*30mm/10\*38mm/10\*480mm/10\*800mm/12\*30mm/  
 12\*38mm/12\*480mm/12\*800mm  
**Basic UDI-DI:** /  
**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: 2020.12.20  
 Position: General Manager  
 Place: Wuxi China

