File No: CE-TCF-001





EC Declaration of Conformity

Regarding Medical Device Directive (93/42/EEC)

including Directive 2007/47/EC

Applicant

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

EU Rep

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Sports Tape, Medical Adhesive Tape, Zinc Oxide Plaster, Wound Plaster, Adhesive Wound Dressing

Type: See Annex of details

Classification: Class I

Rule: According to Rule 1

We confirm our product can meet the requirement of Medical Device Directive and the following harmonized standards.

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2013

EN ISO 10993-1:2009/AC:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2013

Signature

Date .

2019.07

Annex

Product Name	Туре
Sports Tape	1.3cm*13.7m,1.9cm*13.7m,2.5cm*13.7m,3.8cm*13.7m,5.0c
	m*13.7m,7.5cm*13.7m,1.3cm*9.14m,1.9cm*9.14m,2.5cm*9.
	14m ,3.8cm*9.14m ,5.0cm*9.14m ,7.5cm*9.14m
Medical Adhesive Tape	1.25cm*9.14m,2.5cm*9.14m,5cm*9.14m,7.5cm*9.14m,1.25c
	m*4.5m,2.5cm*4.5m, 5cm*4.5m ,7.5cm*4.5m
Zinc Oxide Plaster	2.5cm*3.8m,3.8cm*4.5m,5cm*4.5m 7.5cm*4.5m,10cm*4.5m
Wound Plaster	38*38mm,40*10mm,51*45mm,72*19mm,76*19mm,72*25mm
	,76*25mm,76*30mm,76*38mm,76*45mm,76*50mm,120*20m
46	m
Adhesive Wound	5*7cm,8*10cm,9*10cm,10*10cm,15*10cm,20*10cm,30*10cm
Dressing	无键(C)