

Compliance Report

Applicant: 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: Plaster Of Paris Bandages, Elastic Crepe Bandage, High Elastic Bandage, Cohesive Elastic Bandage, Cast Padding, PBT (Conforming) Bandage

Type: See annex for details

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No.02827

Initial Issue Date: 17 Jul 2019



Signer



Annex to Report (No.02827)

Forlong Medical Co., Ltd

Product Name	Type
Plaster Of Paris Bandages	5cm*2.7m, 7.5cm*2.7m, 10cm*2.7m, 15cm*2.7, 20cm*2.7m, 5cm*3.6m, 7.5cm*3.6m, 10cm*3.6m, 15cm*3.6m, 20cm*3.6m
Elastic Crepe Bandage	5cm*4.5m, 7.5cm*4.5m, 10cm*4.5m, 15cm*4.5m, 20cm*4.5m
High Elastic Bandage	5cm*4.5m, 7.5cm*4.5m, 10cm*4.5m, 15cm*4.5m, 20cm*4.5m
Cohesive Elastic Bandage	2.5cm*4.5m, 5cm*4.5m, 7.5cm*4.5m, 10cm*4.5m, 15cm*4.5m, 20cm*4.5m
Cast Padding	5cm*2.7m, 7.5cm*2.7m, 10cm*2.7m, 15cm*2.7m, 20cm*4.5m, 5cm*3.6m, 7.5cm*3.6m, 10cm*3.6m, 15cm*3.6m, 20cm*3.6m
PBT (Conforming) Bandage	5cm*2.7m, 7.5cm*2.7m, 10cm*2.7m, 15cm*2.7m, 20cm*4.5m

This annex is only valid if attached to the report mentioned above.