

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: Gauze Sponge, Gauze Balls, Gauze Bandage, Gauze Swab, Gauze Roll, Triangular Bandage, Cotton Wool Roll, Cotton Pad, Cotton Ball, Zig-Zag Cotton Wool

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.02828

Initial Issue Date: 17 Jul 2019



Signer



Annex to Report (No.02828)

Forlong Medical Co., Ltd

Product Name	Type
Gauze Sponge	(1cm~120cm) X (1cm~120cm) - (3~48) ply with x-ray (1cm~120cm) X (1cm~120cm) - (3~48) ply without x-ray
Gauze Balls	(6cm~60cm) X (6cm~60cm) -with X-Ray (6cm~60cm) X (6cm~60cm) -without X-Ray
Gauze Bandage	(1cm~120cm) X (1m~20m)
Gauze Swab	(5cm~80cm) X (5cm~80cm) - (3~100) ply with X-ray (5cm~80cm) X (5cm~80cm) - (3~100) ply without X-ray
Gauze Roll	(10cm~120cm) X (1m~3000m) - (1-16) ply with X-Ray (10cm~120cm) X (1m~3000m) - (1-16) ply without X-Ray
Triangular Bandage	(80cm~120cm) X (80cm~120cm) X (110cm~180cm)
Cotton Wool Roll	25g~4000g/roll
Cotton Pad	(5cm~60cm) X (5cm~5m)
Cotton Ball	0.1g~10g
Zig-Zag Cotton Wool	25g~4000g/bag

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