

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: Simple Oxygen Mask, Oxygen Mask With Bag, Nasal Oxygen Tube,
Nebulizer Mask, Suction Connecting Tube, Suction Connecting
Tube With Yankauer Handle,
Suction Catheter, Feeding Tubes, Stomach Tube, Urine Bag

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.02830

Initial Issue Date: 17 Jul 2019



Signer



Annex to Report (No.02830)

Forlong Medical Co., Ltd

Product Name	Type
Simple Oxygen Mask	S, M, L, XL
Oxygen Mask With Bag	S, M, L, XL
Nasal Oxygen Tube	S, M, L, XL
Nebulizer Mask	S, M, L, XL
Suction Connecting Tube	FL70301~FL70310
Suction Connecting Tube With Yankauer Handle	FL70501~FL70510
Suction Catheter	FL70201~FL70210
Feeding Tube	FL70601~FL70610
Stomach Tube	FL70701~FL70710
Urine Bag	FL1001~FL1010

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