



Compliance Report

Applicant: Guangzhou Boda medical supplies Co., Ltd.
Address: 103, Building A, No. 13 Dongsheng Road, Xinya street, Huadu District, Guangzhou, China.

EU Rep Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.

Product: Non-sterile disposable medical mask, Non-sterile medical isolation goggles
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. 03217

Initial Issue Date: 19 May 2020

Betty Bao

Signer



Annex to Report (No. 03217)

Guangzhou Boda medical supplies Co., Ltd.

Product Name	Type
Non-sterile disposable medical mask	The mask body, Nose clip, Ear with
Non-sterile medical isolation goggles	Cover body, Lens, Lock valve, Ribbon

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

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