

CE Technical File



Sunsmed Protective Products Ltd.

Declaration of Conformity

Manufacturer: Sunsmmed Protective Products Ltd.
Address: No.18, Industrial Park., Maozui town, Xiantao city, 433000
Hubei Province, China
European Representative: SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Products: face masks

Classification (MDD Annex IX): **Class I , non-sterile**

We herewith declare that the above mentioned products meet the provision of the following EC Council Directive and Standards. All Supporting documents are retained under the premises of the manufacturer and the notified body.

DIRECTIVES

General applicable directives

Medical Devices Directives:

MDD 93/42/EEC Annex V
EN ISO 13485:2016/AC:2016
EN 14683:2019+AC:2019

Standard:

All applicable harmonized Standard (published in the Official Journal of the European Communities)

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Signature:

For and on behalf of
SUNSMED PROTECTIVE PRODUCTS LIMITED
仙桃盛美工贸有限公司

Name: Nana Sun

Position: Head Regulatory Affairs, Management Representative

Rev.A

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