



CE Notification Confirmation

This is to confirm that, according to the council directive 93/42/EEC (MDD), SUNGO Europe B.V. performed the notification duties and responsibilities as the European authorized representative of:

Dongguan City Risen Medical Products CO., Ltd
No.7 Chuangye Industrial Park Jianshazhou, Wanjiang Dis.
Dongguan Guangdong Province.

The Manufacturer has provided SUNGO Europe B.V. with the EC Declaration of Conformity confirming that the medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 93/42/EEC.

According to 93/42/EEC (MDD), the European Databank on Medical Devices (EUDAMED) is established as of May 1 2011. The Netherlands Competent Authority is notified of the manufacturer's medical devices and has allocated registration number.

Disposable Face Mask

Class I according to Annex IX of 93/42/EEC

GMDN: 35177

CIBG Number: NL-CA002-2020-50175

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 document should be used together with the competence authority notification letter and the Declaration of Conformity issued by the Manufacturer. This document will become to be invalid once the notification status is changed or the EAR agreement is terminated.

Reference Number: EUCAN00056

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For and on behalf of
SUNGO Europe B.V.
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Authorized Signature
Only used for the EU Representative Signature