EC Declaration of Conformity

Manufacturer:

whose single Authorized EU-Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMID: DE/0000047791
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

Disposable Mask

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

Quanzhou 30-Mar-2020

CEO

Place, date

Legally binding signature, Function

EC Declaration of Conformity

Luxus Medical

Verification of CE Registration

Reference Number: JH-ERA-20362V00
Issued Date: March 30, 2020
This Verification will be automatically void if the Notification is rejected by the EU Authorities or upon termination of the EAR.

This is certified that, According to Medical Device 93/42/EEC(MDD), we accepted the appointment to be the Authorized European Representative for products which listed in the attached agreement between below manufacturer and Luxus Lebenswelt GmbH.

The Manufacturer declared that the Medical Device complies with the Directive including all essential requirements.

According to Medical Device 93/42/EEC(MDD), the European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011, the German Competent Authority is notified of the Manufacturer's Medical Devices and has allocated registration numbers shown in:

Disposable Mask, UMDN code: 15-230

Where the manufacturer affixes the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) and standards have and continue to be met.

CE

For and on behalf of
LUXUS LEBENSWELT GMBH
Kochstr.1, 47877 Willich, Germany

Authorized Signature:
Simon Qian
Only used for EU Representative agreements

Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany, info.m@luxuslw.de