Luxus Medical

CERTIFICATE

of MDD Notification

Reference number: JH-ERA-MDR-20266V00
Issued date: March 18, 2020

This certificate will be automatically void if the Notification is rejected by the EU Authorities or upon termination of the EAR.

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

Manufacturer: Guangzhou Biofil Air Purification Materials Co.,Ltd.
Address: Room 201,2ND floor, workshop B,No.1 DouTang Road, YongHe Development Zone Guangzhou China

The Manufacturer declares that the Medical device complies with de 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:

Surgical Mask for Medical Use, UMDN code: 12-530
Registration number: DE/CA20/01-Luxuslebenswelt-38/20

Where the manufacturer affix 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.

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
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