Luxus Medical

Registration Notification

Reference Number: JH-ERA-21203V00
Issued Date: December 11, 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 In Vitro Diagnostic Medical Device 98/79/EC, 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: Shenzhen Lvshiyuan Biotechnology Co., Ltd.

Address: 101,201,301, D Building, No. 2 Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen, China

The Manufacturer declares that the IVD Device complies with the all essential requirements of In Vitro Diagnostic Medical Device 98/79/EC.
According to In Vitro Diagnostic Medical Device 98/79/EC, the European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011, the German Competent Authority is notified of the Manufacturer's In Vitro Diagnostic Medical Devices and has allocated registration numbers shown in:

Flu A & Flu B & COVID-19 Ag Rapid Test

Nomenclature code:15-70-90-90-00

Registration Number: DE/CA20/01-IVD-Luxuslebenswelt-249/20

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.

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