Registration Notification

Reference Number: JH-ERA-MDR-21297V01
Effective Period: 2022.10.19-2025.10.18

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

This is notice that, According to In Vitro Diagnostic Medical Device 98/79/EC, we accept the appointment to be the Authorized European Representative for products which listed in the attached agreement between below manufacturer and Luxus Lebenswelt GmbH.

Manufacturer: Hunan Runmei Gene Technology Co., Ltd.

Address: Room 401-1, Building 3, Shanhe Medical and Health Industrial Park, No. 1048, Zhongqing Road, Shaping Street, Kaifu District, Changsha, Hunan Province, China.

The Manufacturer declares that the IVD Device complies with 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:

Dengue Fever Virus (I, II type) Dual Nucleic Acid Detection Kit (Fluorescence PCR Method),
UMDN code: 15-04-80-11-00

Registration Number: DE/CA20/01-IVD-Luxuslebenswelt-72/22

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
MEDICAL-AMAZON Kochstr.1, 47877 Willich, Germany

Only used for EU Representative Agreements

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