

Registration Notification

Reference Number: JH-ERA-MDR-21388V00 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 Regulation (EU) 2017/746, 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 Regulation (EU) 2017/746.

According to In Vitro Diagnostic Medical Device Regulation (EU) 2017/746, 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:

Disposable Vacuum Blood Collection Tube, UMDN code: 14-01-02-20-00

Registration Number: DE/CA20/00115441

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.

Luxus Lebenswelt GmbH

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For and on behalf of

LUXUS LEBENSWELT GMBH
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Only used for EU Representative Agreements