MedUnion
EC-REP

REGISTRATION NOTIFICATION

Ref. No.: MU-EAR-22136 Date: 24/05/2022

This is to certify that, according to the Council Directive 98/79/EC, MedUnion S.L performed all notification duties and responsibilities as the European Authorized Representatives (EC REP) of:

Manufacturer:	Nanjing Synthgene Medical Technology Co., Ltd.
Address:	Building B6-2,No.9,Weidi Road, Xianlin University Town,Xianlin Subdistrict,Qixia District,Nanjing City,China

The Manufacturer has provided MedUnion S.L. with all the appropriate declarations according to the 98/79/EC Directive-article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated in the Annex I, are fulfilling the applicable requirements of the European Concil Directive 98/79/EC

The notification of the In-Vitro Diagnostic medical devices in the Annex I has been completed by MedUnion S.L on the **24/05/2022** with Registratation number **RPS/3546/2022** in Spanish Medicines and Medical Products Agency.

Conformity Assessment Route: Medical device directive: Council Directive 98/79/EC concerning in vitro diagnostic medical devices (IVDD 98/79/EC).

In-Vitro Diagnostic medical devices: Please see ANNEX I-List of devices (1 page, 3 devices)

Ms Shu Chuan Kuo, Managing Director

MedUnion S.L.

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

ANNEX I- List of Devices

Ref. No.: MU-EAR-22136

Nº	Product Name	Class
1	Monkeypox Virus Antibody Rapid Test Kit	Other
2	Monkeypox Virus Antigen Rapid Test Kit	Other
3	Monkeypox Virus Detection Kit (RT-PCR)	Other