

REGISTRATION NOTIFICATION

Ref. No.: MU-EAR-22101

Date: 09/03/2022

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: Spesera Health Products. Imp & Exp. Trade, Ltd

Address: Goztepe mah. Batisehir cad. No:2/3 Bagcilar/İSTANBUL

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 Council 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 **09/03/2022** with Registratation number **RPS/602/2022** 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, 22 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

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Nº	Product Name	Class
1	COVID-19 Antigen Rapid Test	Other
2	COVID-19 Antigen/InfluenzaA+B Ag Combo rapid test	Other
3	COVID-19 IgG/IgM Rapid test kit	Other
4	Malaria pf/pv One Step Rapid Test	Other
5	Malaria pf/pan One Step Rapid Test	Other
6	fFN Rapid Test	Other
7	D-Dimer Rapid Test Device	Other
8	Influenza A/B Ag Rapid Test	Other
9	Troponin I Rapid Test	Other
10	Typhoid AntigenRapid Test	Other
11	Adenovirus Ag Rapid Test	Other
12	Rotavirus Rapid Test	Other
13	Strep A Rapid Test	Other
14	FOB Rapid Test	Other
15	Mycobacterium Tuberculosis Antibody Rapid Test	Other
16	One Step COC Rapid Test	Other
17	One Step Multi-Drug Test Dip Card	Other
18	H.Pylori Antigen Rapid Test	Other
19	H.Pylori Antibody Rapid Test	Other
20	Syphilis Rapid test	Other
21	Pregnancy one step Rapid test	Other
22	Urine multi strip test	Other