

CERTIFICATE OF NOTIFICATION



EAR Agreement. No.: MU-EAR-22168

Date: 14 October 2022

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

Manufacturer: Assure Tech. (Hangzhou) Co., Ltd.

Address: Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, 310011 Zhejiang, P.R. China

The Manufacturer has provided Medunion S.L. with all the appropriate declarations according to the In Vitro Diagnostic Directive (IVDD) 98/79/EC-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 In Vitro Diagnostic Directive (IVDD) 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: 14 October 2022 with Registration number RPS/5121/2022 in Spanish Medicines and Medical Products Agency.

Conformity Assessment: In Vitro Diagnostic Directive (IVDD) 98/79/EC, Class Others

Medical devices: Please see ANNEX I-List of devices (1 pages, 14 devices)



Dorit Landry
Regulatory Affairs
Director

*This certificate will be automatically void if the notification is rejected by the EU authorities or upon termination of the EAR agreement.

ANNEX I- LIST OF DEVICES

EAR Agreement. No.: MU-EAR-22168

N°	Commercial Name	Classification
1	Adenovirus&Norovirus Antigen Fecal Test Kit	Others
2	Adenovirus&RSV Antigen Nasal Test Kit	Others
3	COVID-19&Influenza A/B&Adenovirus Antigen Nasal Test Kit	Others
4	COVID-19 & Influenza A/B& Adenovirus&RSV Antigen Nasal Test Kit	Others
5	Dengue & Zika IgG/IgM combo Test Kit	Others
6	Dengue& Zika NS1 combo Test Kit	Others
7	HAV IgG/IgM Rapid Test Kit	Others
8	HAV IgM Rapid Test Kit	Others
9	HEV IgG/IgM Rapid Test Kit	Others
10	HEV IgM Rapid Test Kit	Others
11	Rotavirus&Adenovirus Antigen Fecal Test Kit	Others
12	Rotavirus&Adenovirus&Norovirus Antigen Fecal Test Kit	Others
13	Strep A Antigen Test Kit	Others
14	Rotavirus&Norovirus Antigen Fecal Test Kit	Others