CERTIFICATE OF NOTIFICATION

MEDUNION
EC-REP

EAR Agreement. No.: MU-EAR-23221 Date: 13 November 2023

This is to certify that, according to the Council Regulation (EU) 2017/746, MedUnion S.L performed all notification duties and responsibilities as the European Authorized Representatives (EC REP) of:

Manufacturer: Bioantibody Biotechnology Co., Ltd.

Address: Room 903 & 905, Building C6, No.9, Weidi Road, Qixia District, Nanjing, China

The Manufacturer has provided MedUnion S.L. with all the appropriate declarations according to the Regulation (EU) 2017/746-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 Regulation (EU) 2017/746.

The notification of the In-Vitro Diagnostic medical devices in the Annex I has been completed by MedUnion S.L on the: 13 November 2023 with Registration number RPS/2772/2023 in Spanish Medicines and Medical Products Agency.

Conformity Assessment Route: Regulation (EU) IVDR 2017/746 (In vitro Diagnostic Medical Devices Regulation-IVDR), Class A.

In vitro Diagnostic medical devices: Please see ANNEX I-List of devices (1 page, 2 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.

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ANNEX I-
LIST OF DEVICES

EAR Agreement. No.: MU-EAR-23221

Nº	Commercial Name	Classification
1	Handheld Biochemical Immunoassay Analyzer	Class A
2	Handheld Urine Analyzer	Class A