EU Declaration of Conformity

Manufacturer: HANGZHOU ALLTEST BIOTECH CO., LTD.
Address: #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R. China
Single Registration Number: CN-MF-000010710

European Representative: MEDNET EC-REP GmbH
Address: Borkstrasse 10, 48163 Muenster, Germany
Single Registration Number: DE-AR-000000002

Product Name: Fluorescence Immunoassay Analyzer
Analyte: For quantitative or qualitative detection of human samples with specific in vitro diagnostic test units including Inflammation Markers, Tumor Markers, Nephrology, Diabetes, Cardiac Markers, Coagulation, Endocrinology, Autoimmunity, Infectious Diseases and etc.

REF	AFR-100/ AFR-100S	AFR-200/ AFR-200S	AFR-300/ AFR-300S	AFR-301/ AFR-302	AFR-400

Model: Instrument
Classification according to Rule 5(b) of IVDR Annex VIII: Class A
Conformity Assessment Procedure: Annex II and III
EMDN Code: W0201020201
Basic UDI-DI: 6970277510002PYF

We, HANGZHOU ALLTEST BIOTECH CO., LTD, herewith declare that the EU declaration of conformity is issued under the sole responsibility of above manufacturer. The above mentioned product is in conformity with following Regulation and Standards:

Regulation Applied: REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
Standard Applied: EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, EN 13612:2002/AC:2002, IEC 62366-1:2015, IEC 61326-1:2012, IEC 61326-2-6:2012, EN 61010-1:2010+A1:2019, EN 61010-2-101:2017, IEC 62304:2015, EN ISO 18113-1:2011, EN ISO 18113-3:2011.

Place, Date of First Issue of DOC: in Hangzhou on 2022-02-25
Date of Issue of DOC on 2024-02-01

Signature:
Name: Gao Fei
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