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-00000002

Product Name: Cup Reader
Analyte: For reading the results of the Drug of Abuse urine cup and displaying the qualitative results
REF: ACR-100
Brand: EZDitell™
Model: Instrument
Classification according to Rule 5(b) of IVDR Annex VIII: Class A
Conformity Assessment Procedure: Annex II and III
EMDN Code: W02010701
Basic UDI-DI: 6970277510002RYK

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 15223-1:2016, IEC 62366-1:2015, IEC 61326-1:2012, IEC 61326-2-6:2012, IEC 61010-1:2010/AMD1:2016, IEC 61010-2-101:2018, IEC 61010-2-081:2015, 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

Signature:
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Position: General Manager

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