EC Declaration of Conformity

Manufacturer:
Name: HANGZHOU ALLTEST BIOTECH CO., LTD.
Address: #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R. China

European Representative:
Name: MedNet EC-REP GmbH
Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: HIV 1.2 Rapid Test Cassette (Whole Blood/Serum/Plasma)
Cat. No.: IHI-402
Ref: C3 1017
Model: Cassette
Analyte: Detection of antibodies to HIV (Human Immunodeficiency Virus) type 1&2 in Whole Blood/Serum/Plasma
Classification: Annex II, List A of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex IV
GMDN Code: 65847

We, HANGZHOU ALLTEST BIOTECH CO., LTD., herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned products meet the corresponding national laws, the provisions of the following EC Council Directives, Standards and Common Technical Specifications. All supporting documentations are retained at the premises of the manufacturer.

General Applicable Directives:
Directive 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices
Standard Applied: EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016
Common Technical Specifications: COMMISSION DECISION 2002/364/EC Rev. 2021.03.02

Notified body: CeCert Sp. z o.o. (ID: 2934)
Address: ul. Żurawia 32/34 lok.49 Warszawa, Poland
(EC) Certificates: CeCert/096/W/E.1(EC DESIGN-EXAMINATION) &. CeCert/097/W/E.1 (FULL QUALITY ASSURANCE SYSTEM)
Expiry Date of the Certificate: 2022.05.13-2025.05.26
Start of CE Marking: 2022.05.13
Place, Date of First Issue of DOC: in Hangzhou on 2022.05.13
Signature:_____
Name: Gao Fei (Position: General Manager)

Hangzhou AllTest Biotech Co.,Ltd.
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