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 GmbH
Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: See attachment 1
Model: See attachment 1
Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III
EDMA Code: See attachment 1

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 transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

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 ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of Issue: in Hangzhou on 11/12/2020

Signature: Soar Gao
Name: Soar Gao (Position: General Manager)

Hangzhou AllTest Biotech Co.,Ltd.
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Attachment 1

Catalog NO.	Product Name	EDMA Code	Model
IMA-402	Malaria P.f. Rapid Test Cassette	15 70 05 01 00	Cassette
ISTB-501	Strep A Rapid Test Dipstick (Control Line in Blue)	15 70 01 03 00	Dipstick

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