

EC Declaration of Conformity

Manufacturer:

Name: HANGZHOU ALLTEST BIOTECH CO., LTD.

Address : #550, Yin Hai 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 excluding point 6

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.

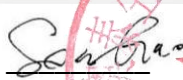
DIRECTIVES

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 13/11/2020

Signature: 

Name: Soar Gao (Position: General Manager)

Attachment 1

Catalog NO.	Product Name	EDMA Code	Model
DAM-402	AMP Rapid Test Cassette	12 70 09 01 00	Cassette
DBZ-402	BZO Rapid Test Cassette	12 70 09 04 00	Cassette
DCO-402	COC Rapid Test Cassette	12 70 09 06 00	Cassette
DED-402	EDDP Rapid Test Cassette	12 70 09 07 00	Cassette
DMD-402	MDMA Rapid Test Cassette	12 70 09 90 00	Cassette
DME-402	MET Rapid Test Cassette	12 70 09 02 00	Cassette
DMO-402	MOP Rapid Test Cassette	12 70 09 90 00	Cassette
DMT-402	MTD Rapid Test Cassette	12 70 09 07 00	Cassette
DTH-402	THC Rapid Test Cassette	12 70 09 05 00	Cassette
DTM-402	TML Rapid Test Cassette	12 70 09 90 00	Cassette