

## *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

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: 

Name: Soar Gao (Position: General Manager)



## Attachment 1

<b>Catalog NO.</b>	<b>Product Name</b>	<b>EDMA Code</b>	<b>Model</b>
FHC-101	Pregnancy (hCG) Rapid Test Dipstick	12 70 05 02 00	Dipstick
FHC-102	Pregnancy (hCG) Rapid Test Cassette	12 70 05 02 00	Cassette
FHC-F103	Pregnancy (hCG) Rapid Test Midstream	12 70 05 02 00	Midstream