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: HCG Rapid Test
Model: Attachment 1
Classification: Self-test Devices of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex IV
EDMA Code: 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 ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN 13532:2002, EN ISO 15223-1:2016
Notified body: TUV SUD Product service GmbH, Ridlerstrasse 65, 80339 Munich, Germany
ID: 0123
(EC) Certificate(s): V1 095123 0008 Rev.03
Expire date of the Certificate: 2024-05-26
Start of CE Marking: 2016-09-14
Place of Issue: in Hangzhou

Signature: _____ 24/05/2021
Name: GAO FEI (Position: General Manager) Date

Hangzhou AllTest Biotech Co.,Ltd.
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Attachemnt 1

Catalog NO.	Product Name	EDMA Code	Model
FHC-U103H	Pregnancy (hCG) Enhanced Sensitivity Rapid Test Midstream	12 70 05 02 00	Midstream
FHC-F103H	Pregnancy (hCG) Rapid Test Midstream	12 70 05 02 00	Midstream

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