

# 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 (Group) Name: FOB (Fecal Occult Blood) Rapid Test (Feces)

Cat. No.: See attachment 1

Analyte: See attachment 1

Model: See attachment 1

Classification: Self-testing Device of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex IV

EDMA Code: 12 70 03 90 00

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 (0123)

(EC) Certificate(s): V1 095123 0008 Rev.04

Expire date of the Certificate: 2025-05-26

Transitional Period: From 2025-05-26 to 2027-12-31 according to Regulation EU 2024/1860 confirmed with TUV SUD confirmation letter CLI 095123 0015

Start of CE Marking: 2016-09-14

Place, Date of First issue of DOC: in Hangzhou on 2016-09-14

The Date of Issue of DOC on 2025-05-06

Signature: 

Name: GAO FEI (Position: General Manager)

HANGZHOU ALLTEST BIOTECH CO., LTD.

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Attachment 1

Catalog NO.	Product Name	Analyte	Model
TFO-601H	FOB Rapid Test Dipstick (Feces)	Fecal Occult Blood in human Feces	Dipstick
TFO-602H	FOB Rapid Test Cassette (Feces)	Fecal Occult Blood in human Feces	Cassette

