

## Manufacturer:

Name: HANGZHOU ALLTEST BIOTECH CO., LTD.

Address : #550, Yin Hai Street, Hangzhou Economic &amp; Technological Development Area, Hangzhou -310018, P.R. China

## European Representative:

Name: MedNet GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: Sperm Concentration Rapid Test

Model: Cassette

Classification: Self-test Devices of IVDD 98/79/EC

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

EDMA Code: 12 70 05 90 00

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: IVDD 98/79 EC, EN ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN 23640:2015, EN 13641:2002, EN 1041:2008, EN13532 2002, EN ISO 15223-1:2016

Notified body: TUV SUD Product service GmbH, Ridlerstrasse 65, 80339 Munich, Germany

ID: 0123

(EC) Certificate(s): V1 17 06 95123 008

Expire date of the Certificate: 2021-06-14

Start of CE Marking: 2016-09-14

Place, Date of Issue: in Hangzhou on 05/01/2018Signature: 

Name: Soar Gao

Position: General Manager