

 Hangzhou Singclean Medical Products Co., Ltd.	Technical File	File No.	TCF-HCG-B-12
		Version No.	A/6
		Rev. Date	2022-03-10

EC Declaration of Conformity

Manufacturer: Hangzhou Singclean Medical Products Co., Ltd

No. 125 (E), 10th Street, Hangzhou Qiantang New Area, Zhejiang, China 310018

European Representative: Obelis S.A

Bd. Général Wahis, 53

1030 Brussels, Belgium

Product: Human Chorionic Gonadotropin (HCG) Pregnancy Test Kit (Colloidal Gold)

Model: Strip, Cassette, Midstream

Classification: Self-testing

EDMS Code: 12 70 05 02

Conformity assessment Route: Annex IV excluding 4 and 6, IVDD 98/79/EC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices and we take the sole responsibility of the products. All supporting documentation is retained under the premises of the manufacturer.

Standards applied:

EN ISO 13485:2016+A11:2021	EN ISO 18113-1:2011
EN ISO 14971:2019	EN ISO 18113-4:2011
EN 13612:2002	EN ISO 15223-1:2016
EN 13641:2002	EN 13532:2002
EN 13975:2003	EN 62366-1:2015+A1:2020
EN ISO 23640:2015	EN ISO 17511:2003

Notified Body: TÜV SÜD PRODUCT SERVICE GMBH (NB.NO.: 0123)

Ridlerstraße 65 80339 MÜNCHEN GERMANY

EC Certificate No.: V1 097027 0002 Rev.03

Valid date: 2024-05-26

Place of Issue: Hangzhou, China

Signature/Date:  2022. 03. 10

Name: Sun Weiqing

Position: General Manager