

## EC Declaration of Conformity

### Regarding to Regulation (EU) 2017/746 on IVD medical device

Manufacturer: Hangzhou Singclean Medical Products Co., Ltd.

Manufacturer address: No. 125(E), 10th street, Hangzhou Qiantang Area, Zhejiang, China 310018

SRN: CN-MF-000014098

Authorized representative: Obelis S.A

Address: Bd. Général Wahis, 53, 1030 Brussels, Belgium

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

Basic UDI-DI: 69360201208J

Model	Package variants	UDI-DI code
Strip	1 test/box	06936020109376
	5 tests/box	06936020109475
	25 tests/box	06936020109482
	50 tests/box	06936020109864
	100 tests/box	06936020109499
Cassette	1 test/box	06936020109383
	5 tests/box	06936020109505
	25 tests/box	06936020109833
	40 tests/box	06936020109512
	50 tests/box	06936020106900
Midstream	1 test/box	06936020109390
	20 tests/box	06936020109529

Classification: Class B (according to Rule 4 of Annex VIII of Regulation (EU) 2017/746)

EMDN code: W0102160302 - HCG - RT & POC

Intended purpose:

The human chorionic gonadotropin (HCG) pregnancy test kit is a rapid, one-step lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (HCG) in urine to aid in the detection of pregnancy.

This test is for women who are planning pregnancy or suspected pregnant to aid in the early detection of pregnancy. This test is suitable for self-testing, professional use and near-patient testing.

The following notified body is exclusively entrusted to assess compliance:

Notified body: TÜV SÜD PRODUCT SERVICE GMBH (No.: 0123)

Address: Ridlerstraße 65, 80339 MÜNCHEN, GERMANY

Conformity Assessment Procedure: Annex IX of IVDR

Certificate No.: V10 097027 0006 Rev. 00

Expiry date of the certificate: 2029-04-23

We herewith declare that the manufacturer is responsible for the EU declaration of conformity. We confirm that the device covered by the present declaration is in conformity with Regulation (EU) 2017/746 on IVD medical device and the following CS or harmonized standards.

Applicable harmonized standards:

EN ISO 13485:2016+A11:2021

EN ISO 18113-1:2011

EN ISO 23640:2015

EN ISO 14971:2019

EN ISO 18113-4:2011

EN ISO 17511:2021

EN ISO 15223-1:2021

EN ISO 18113-2:2011

Applicable other standards:

EN 13641:2002

EN 13532:2002

EN 62366-1:2015+A1:2020

EN 13612:2002

ISO 20916:2019

Applicable Common Specifications: NA

Place of issue: Hangzhou, Zhejiang, China

Name: Weiqing Sun on behalf of Hangzhou Singclean Medical Products Co., Ltd.

Position: General Manager

Signature: \_\_\_\_\_



Date: \_\_\_\_\_

2024.06.03