

EU DECLARATION OF CONFORMITY

Manufacturer: Hangzhou Sejoy Electronics& Instruments Co.,Ltd.
Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic
Development Zone, Hangzhou City 311100 Zhejiang China

European Authorized Representative: Shanghai International Holding Corp.GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: hCG One Step Pregnancy Test

Specification: Strip, Cassette, Midstream

Classification: Self-testing device not listed under Annex II of Directive
98/79/EC

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstr.65. 80339 München, Deutschland

Notified Body No.: CE 0123

EC Certificate No.: V1 095295 0002

EC Certificate valid until: 2025.05.26

Conformity assessment route: Annex IV, excluding Sections 4 and 6 of Directive 98/79/EC

Applicable Standards: EN ISO 13485:2016, EN ISO 14971:2012,
EN 13532:2002, EN ISO 23640:2015, EN ISO 13612:2002,
EN ISO 17511:2003, EN 13975:2003,
EN ISO 18113-1:2011, EN ISO 18113-4:2011,
EN ISO 15223-1:2016, EN 13641:2002

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

杭州世佳电子有限公司
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.

Hangzhou, May 02, 2022

Place, date



General Manager

Legally binding signature, Position