TÜVRheinland®

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 2041176-1

Manufacturer: Hangzhou Clongene Biotech Co., Ltd.
No.1 Yichuang Road,
Yuhang Sub-district, Yuhang District,
Hangzhou
311121 Zhejiang
P.R. China

Products:
- HCG Pregnancy Rapid Tests
- LH Ovulation Rapid Tests

Replaces Approval, Registration No.: HL 60147053 0001

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

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TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.