

# EC Certificate



Full Quality Assurance System  
Directive 98/79/EC on  
Annex IV excluding (4)

Registration No.:

Manufacturer:

(Hangzhou) Co., Ltd.  
Building No. 1018, Shushu Rd.,  
Cangqian, Hangzhou District,  
Hangzhou  
311121 Zhejiang  
P.R. China

Products:

- HCG Pregnancy Rapid Tests

Replaces Approval, Ref: 0129087 0001

The Notified Body hereby declares that the requirements of Directive 98/79/EC 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 according to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. The products are placed on the market of List A devices covered by this certificate as an EC design. The manufacturer is responsible according to Annex IV, section 4 and a verification of manufacturing process is required.

Report No.:

Effective date:

Expiry date:

Issue date:

2025-05-26

2022-03-13



Fuxiu Sheng  
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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 0129087 0001