

# EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Tianjin New Bay Bioresearch Co., Ltd.  
No.1 Jianshe Road, Ba Li Tai Industry Area, Jinnan  
District, 300350 Tianjin, China

Emergo Europe  
Prinsessegracht 20,  
2514 AP The Hague  
The Netherlands

We, the manufacturer, herewith declare that the products

**Pregnancy Urine Tests for Self-testing**

**Model: Alvita**

**EDMA Code 12. 70.05. 02**

meet the provisions of Directive 98/79/EC which apply to them.

The medical device has been assigned to devices for self-testing according to the Directive 98/79/EC. It bears the mark

**CE 0197**

The product concerned has been designed and manufactured under a quality management system according to Annex IV of Directive 98/79/EC.

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body

**TÜV Rheinland LGA Products GmbH**  
**Tillystraße 2, 90431, Nürnberg, Germany**

Certificate No.: SX2012972-1

Report No.: 19013008810

Expiry date: 2024.03.11

following the procedure relating to the EC Declaration of Conformity set out in Annex IV of Directive 98/79/EC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Tianjin New Bay Bioresearch Co., Ltd.

Address: No.1 Jianshe Road, Ba Li Tai Industry Area, Jinnan District, 300350 Tianjin, China

Tianjin 2021-3-10  
Place, Date



Tong Shan  
Legally binding signature, Function