

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

Ovulation Predictor 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


Tianjin New Bay Bioresearch Co., Ltd.
天津新湾生物科技有限公司
Legally binding signature, Function