



EC Certificate

Full Quality Assurance System Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6) (List A and B and devices for self-testing)

No. V1 084924 0002 Rev. 01

Manufacturer:

Hubei MEIBAO Biotechnology Co., Ltd.

No.5 Hongfu Road, Shayang Economic Development Zone

448200 Jingmen City

PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH

(Europe)

Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies): Self tests

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report no.:

BJ18103207

Valid from:

2018-11-30

Valid until:

2023-10-10

Date.

2018-11-30

Stefan Preiß

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Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 084924 0002 Rev. 01

Model(s): Human chorionic gonadotropin Colloidal gold test,

Human luteinizing hormone Colloidal gold test,

Fecal Occult Blood Colloidal gold test.

Facility(ies): Hubei MEIBAO Biotechnology Co., Ltd.

No.5 Hongfu Road, Shayang Economic Development Zone, 448200 lingmen City, PEOPLE'S REPUBLIC OF CHINA

