Verification of CE Registration

Certificate No.: BR-20200305-002

This is to certify that during the examination of the Technical Documentation provided by the manufacturer:

Name: Hangzhou Bioer Technology Co., Ltd.

Address: 1192 BinAn Rd., Binjiang District, 310053 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

On its product as follows:

Product name: Sample Preservative Fluid

Type/model: 1mL/tube, 2mL/tube, 3mL/tube, 4mL/tube, 100mL, 200mL, 1000mL

Classification: Other IVD Product

No Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected, and the aforementioned device complies with Directive including all essential requirements.

The manufacturer has provided all the appropriate declaration according to the Directive 98/79/EC - article 10 requirements including the EC Declaration of Conformity confirming that this In vitro diagnostics medical device, as stipulated above, is fulfilling the applicable requirements of the Directive 98/79/EC.

The notification of aforementioned device has been completed by the European Representative in Germany. The German Competent Authority is notified of the manufacturer's in vitro medical devices and has allocated registration.

Issue Date:2020-03-06

Date of expiry:2022-05-25

Justin

SIGNATURE

CE

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