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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-245.10.07



Product Service

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 101949 0003 Rev. 00

Manufacturer: **Cofoe Medical Technology Co., Ltd.**
816 Zhenhua Road
Yuhua District
410000 Changsha, Hunan
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Blood glucose measuring systems for self testing**
Pregnancy test for self testing

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1_101949_0003_Rev._00

Report no.: GZ2137904

Valid from: 2022-05-06

Valid until: 2025-05-26

Date, 2022-05-06

Christoph Dicks
Head of Certification/Notified Body



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 101949 0003 Rev. 00

Model(s): **Blood Glucose Monitoring System (include Blood Glucose Meter, Blood Glucose Test Strip and Glucose Control Solution), HCG Pregnancy Test**

Facility(ies): **Cofee Medical Technology Co., Ltd.**
816 Zhenhua Road, Yuhua District, 410000 Changsha, Hunan,
PEOPLE'S REPUBLIC OF CHINA

Cofee Medical Technology Co., Ltd.
579 Zhenhua Road, Yuhua District, 410000 Changsha, Hunan,
PEOPLE'S REPUBLIC OF CHINA