

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Manufacturer: **BioTeke Corporation (Wuxi) Co., Ltd.**
No. 90, Huiming Road, Huishan, Wuxi, Jiangsu, 214000
China

Single registration number: CN-MF-000007517

Authorized representative: **MedUnion S.L.**
Carrer de Tapioles, 33, 2-1, 08004, Barcelona
Spain

Single registration number: ES-AR-000019366

Notified Body Sertio Oy declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the

REGULATION (EU) 2017/746 on In Vitro Diagnostic Devices

have been met for the products listed in this certificate.

The above mentioned manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation.

Certificate validity is subject to manufacturer fulfilling the obligations arising from the Annex IX of the aforementioned regulation. Validity of the certificate is subject to following the General terms of Business by Sertio Oy and Terms of conformity assessment of IVD medical devices.

NOTE: For class A sterile devices: "Audit by the notified body was limited to the aspects of manufacture concerned with securing and maintaining sterile conditions".

For placing in the market class D devices, companion diagnostic devices, devices for self testing and devices for near patient testing, in addition to this certificate a separate EU technical documentation assessment certificate according to Annex IX chapter II is required and has been issued with certificate number: EU-TDA-FI-43117-800031-2025

Certificate number	EU-QMS-FI-40845-800031-2025
Issue date	30.05.2025
Valid from	30.05.2025
Expiry date	30.05.2030

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PRODUCTS

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Class C for self testing

IVR 0503	Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
IVP 3007	Immunoassays
W0105	Infectious diseases

Certificate history

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Version	Date issued	Description
1	30.5.2025	Initial issue