# EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

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| Manufacturer: | **BioTeke Corporation (Wuxi) Co., Ltd.**<br>No. 90, Huiming Road, Huishan, Wuxi, Jiangsu, 214000<br>China |
| Single registration number: | CN-MF-000007517 |
| Authorized representative: | **MedUnion S.L.**<br>Carrer de Tapioles, 33, 2-1, 08004, Barcelona<br>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

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|---|---|
| Certificate number | EU-QMS-FI-40845-800031-2025 |
| Issue date | 09.07.2026 |
| Valid from | 09.07.2026 |
| Expiry date | 30.05.2030 |

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# PRODUCTS

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|---|---|
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**Class C for self testing**

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| 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 |

**Class B for self testing**

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| IVR 0607 | Devices intended to be used for detection of pregnancy or fertility testing |
| IVP 3007 | Immunoassays |
| W0102 | Immunochemistry (Immunology) |

# Certificate history

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| Version | Date issued | Description |
|---|---|---|
| 1 | 30.5.2025 | Initial issue |
| 2 | 09.7.2026 | Added class B self-testing device under IVR 0607 |