

CE Technical Documentation Review Report

Applicant: BioTeke Corporation (Wuxi) Co., Ltd
Address: 4th floor, D5, No.1719,Huishan Avenue, Wuxi, China 214174
Product: Cell-Free DNA Storage Tube, Blood RNA Storage Tube, Nucleic Acid Extraction Kit
Model: See Annex

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to IVDD (In Vitro Diagnostic Medical Directive, 98/79/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

No. EU 190016

Issue Date: July 9, 2019

Valid Until: July 8, 2024



General Manager (Signature)

This report is the property of POSI and should be returned to POSI upon request. Whenever the devices listed in this Report were changed or the directive/standards were changed, this report shall be reissued.

ANNEX

Product Name	Model:
Cell-Free DNA Storage Tube,	ST2001, ST2002
Blood RNA Storage Tube	ST1001, ST1002
Nucleic Acid Extraction Kit	AU18112, AU4001, AU19014, AU1201, AU70011, AU7011, AU31111, AU46111, AU52012, AU17011, AU10111, DP1801, DP1802, DP1901, DP1902, DP4611, DP4612, DP4613, DP3111, DP3112, DP3113, DP3114, RP5401, RP5402

END OF THE ANNEX

