

Technical file review report

Report No: IVD GZES1908021769ME

Applicant: Shenzhen Shineway Technology Corporation

**Room 1206, Block 18B, ZhonghaiXin City of Innovative Industry, Gan Li 2nd Road
NO. 11 Jihua Street, Longgang District, Shenzhen, Guangdong, China**

Product Name: PCR Nucleic Acid Analyzer

Model Number: SWM-01

Date: 2020-01-16

Date of expiry: 5 years

**Review result: Comply the Essential Requirements of the EC Directive 98/79/EC for In Vitro
Diagnostic Medical Devices (Doc. No.: SW-SWM01-CE-EN-A0)**


Fly Lu

Laboratory Technical Manager
SGS-CSTC Standards Technical Services
Co., Ltd. E&E Lab Guangzhou



While all due care and skill was exercised in carrying out this assessment, SGS-CSTC accepts responsibility only for proven gross negligence. This certificate relates only to the medical device as described in the technical file reviewed on the date shown. Conformance to all the regulatory requirements is the sole responsibility of the manufacturer including the manufacture and quality control of the products.

This is not a legal document and cannot be used as such. This certificate remains the property of SGS-CSTC Standards Technical Services Co., Ltd. to whom it must be returned on request.

Copyright of this statement is owned by SGS-CSTC Standards Technical Services Co., Ltd. and may not be reproduced other than in full and with the prior approval of the General Manager. This verification is subjected to the governance of the General Conditions of Services, printed overleaf.

Member of SGS Group (Société Générale de Surveillance)