



DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Core Technology Co., Ltd.
Address: Room 100, C Building, No.29 Life Park Rd., Changping District, Beijing 102206, P.R.China
EC Representative: SUNGO Cert GmbH
Address: Harffstr. 47,40591 Düsseldorf, Germany

Product Name: TP Syphilis Test
Specification: Cassette and Strip
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN 13612:2002/AC:2002	EN ISO 23640:2015	EN ISO 14971:2019
EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO15223-1:2016
EN 62366-1:2015	EN 13641:2002	

Signature: 

Position: RM

Date: 2022-01-13

Place: Beijing / China

北京库尔科技有限公司
CORE TECHNOLOGY CO., LTD.