



DECLARATION OF CONFORMITY

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

Manufacturer: Beijing OriginPoly Bio-Tec Co., Ltd.
3rd Floor, No. 18 Building, Yard 50, Huatuo Road, Daxing Biomedical

Address: Industry Base, Zhongguancun Science and Technology Park, Daxing District, Beijing.

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: DNA Methylation Detection Kit for Cervical Cancer (Real-time PCR)

Specification: 24 tests , 48 tests

Classification: Others (IVDD)

Conformity Assessment Annex III of In Vitro Diagnostic Directive (98/79/EC)

Procedure:

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 ISO 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011
EN 13612:2002+AC:2002 EN ISO 23640:2015 EN 13641:2002
EN ISO 20417:2021

Signature: 

Position: GM

Date: 2021/10/28

Place: Bei Jing/China

