



# 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 Endometrial Cancer ( Real-time PCR)


**Specification:** 24 tests , 48 tests

**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 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: 2022.08.30

Place: Bei Jing/China

