



# DECLARATION OF CONFORMITY

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

**Manufacturer:** Zhejiang Concern Biological Technology Co., Ltd  
**Address:** 2F Building 2, 48 Dongshan Road, Jiangdong Sub-district, Yiwu, Zhejiang, China

**EC Representative:** SUNGO Europe B.V.  
**Address:** Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

**Product Name:** Specimen Containers  
**Specification:** 5mL, 10mL, 20mL, 25mL, 30mL, 40mL, 60mL, 80mL, 90mL, 120mL

**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 15223-1: 2016  
EN ISO 20417: 2021

Signature: 

Position: Director

Date: 2022.1.19

Place: Zhejiang / China

