



# DECLARATION OF CONFORMITY

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

**Manufacturer:** CHANGDE BKMAM BIOTECHNOLOGY CO., LTD  
**Address:** 1st Floor, building 1, East of New material industrial zone, Linli Economic Development Zone, Changde, Hunan Province, China

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

**Product Name:** PIPETTE TIPS WITH FILTER  
**Model:** 10ul,20ul,50ul,100ul,200ul,300ul,1000ul,1250ul,5000ul,10000ul

**Classification:** Others (IVDD)  
**Conformity Assessment Procedure:** Annex III of In Vitro Diagnostic Directive (98/79/EC)



We herewith 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 15223-1:2021      EN ISO 20417: 2021

**Signature:** 黄思思  
**Position:** GM

**Date:** 2022. 3. 17  
**Place:** Changde/ China

