



DECLARATION OF CONFORMITY

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

Manufacturer: PakGent Bioscience (Suzhou) Co., Ltd.
Address: Floors 1-3, building 33, No. 228, Gongtang Road, Luzhi Town,
Wuzhong District, Suzhou, China.

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

Product Name: Pipette Tips
Models: See Annex
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: 2021

EN ISO 20417: 2021

Signature: Jacky Maence (Suzhou) Co., Ltd.
Position: Director
Date: 2022.02.20
Place: Suzhou / China



Annex

Product Name	Model
Pipette Tips	UFPT-10R; UFPT-F-10; UFPT-REF-10; UFPT-10B; UFPT-F-10B; UFPT-10ER; UFPT-F-10E; UFPT-10EB; UFPT-F-10EB; UFPT-10ETR; UFPT-F-10ET; UFPT-10ETB; UFPT-F-10ETB; UFPT-200R; UFPT-F-20; UFPT-REF-200; UFPT-200B; UFPT-F-20B; UFPT-F-50; UFPT-F-100; UFPT-F-200; UFPT-F-50B; UFPT-F-100B; UFPT-F-200B; UFPT-200ER; UFPT-F-200E; UFPT-REF-200E; UFPT-300B; UFPT-F-200EB; UFPT-1000R; UFPT-F-1000; UFPT-1000B; UFPT-F-1000B; UFPT-1000ER; UFPT-F-1000E; UFPT-REF-1000E; UFPT-1000EB; UFPT-F-1000EB; UFPT-200SR; UFPT-F-200S; UFPT-200SB; UFPT-F-200SB; UFPT-1000MR; UFPT-F-1000M; UFPT-1000MB; UFPT-F-1000MB; UFPT-10R-L; UFPT-F-10-L; UFPT-REF-10-L; UFPT-10B-L; UFPT-F-10B-L; UFPT-10ER-L; UFPT-F-10E-L; UFPT-10EB-L; UFPT-F-10EB-L; UFPT-10ETR-L; UFPT-F-10ET-L; UFPT-10ETB-L; UFPT-F-10ETB-L; UFPT-F-50-L; UFPT-F-100-L; UFPT-F-200-L; UFPT-50B-L; UFPT-F-100B-L; UFPT-F-200B-L; UFPT-200R-L; UFPT-F-20-L; UFPT-REF-200-L; UFPT-200B-L; UFPT-F-20B-L; UFPT-200ER-L; UFPT-F-200E-L; UFPT-REF-200E-L; UFPT-300B-L; UFPT-F-200EB-L; UFPT-1000R-L; UFPT-F-1000-L; UFPT-1000B-L; UFPT-F-1000B-L; UFPT-1000ER-L; UFPT-F-1000E-L; UFPT-REF-1000E-L; UFPT-1000EB-L; UFPT-F-1000EB-L; UFPT-200SR-L; UFPT-F-200S-L; UFPT-200SB-L; UFPT-F-200SB-L; UFPT-1000MR-L; UFPT-F-1000M-L; UFPT-1000MB-L; UFPT-F-1000MB-L; RT20R; RT20R-L; RT20RF RT20RF-L; RT20B; RT20B-L; RT20-REF; RT20-REF-L; RT200R; RT200R-L; RT200RF; RT200RF-L; RT200B; RT200B-L; RT200-REF; RT200-REF-L; RT1000R; RT1000R-L; RT1000RF; RT1000RF-L; RT1000B; RT1000B-L; RT1000-REF; RT1000-REF-L; RT050T; RT050T-L; RT050TF; RT050TF-L; RT200T; RT200T-L; RT200TF; RT200TF-L; RT1000T; RT1000T-L; RT1000TF; RT1000TF-L; RT050TX; RT050TX-L; RT050TFX; RT050TFX-L; RT200TX; RT200TX-L; RT200TFX; RT200TFX-L; RT1000TX; RT1000TX-L; RT1000TFX; RT1000TFX-L; RT050H; RT050H-L; RT050HF; RT050HF-L; RT300H; RT300H-L; RT300HF; RT300HF-L; RT1000H; RT1000H-L; RT1000HF; RT1000HF-L; RT050HX; RT050HX-L; RT050HFX; RT050HFX-L; RT300HX; RT300HX-L; RT300HFX; RT300HFX-L; RT1000HX; RT1000HX-L; RT1000HFX; RT1000HFX-L; RT050B; RT050B-L; RT050BF; RT050BF-L; RT250B; RT250B-L; RT250BF; RT250BF-L; RT250A; RT250A-L; RT250AF; RT250AF-L;