



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: Serological Pipette

Models: SPTS01; SPTB01; SPTS02; SPTB02; SPTS05; SPTB05; SPTS10;
SPTB10; SPTS25; SPTB25; SPTS50; SPTB50;

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: Jacley Ma.

Position: Director

Date: 2024.20

Place: Suzhou / China

