CE

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:	Package Bottles
Models:	WMPB008; WMPB015; WMPB030; WMPB060; WMPB125; WMPB250; WMPB500; WMPB1000; WMPB008A; WMPB015A; WMPB030A; WMPB060A; WMPB125A; WMPB250A; WMPB500A; WMPB1000A; NMPB030; NMPB060; NMPB125; NMPB250; NMPB500; NMPB1000; NMPB030A; NMPB060A; NMPB125A; NMPB250A; NMPB500A; NMPB1000A;
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 ma

Position: Director

Date: 2022.4.20

Place: Suzhou / China

PakGent Bioscience (Suzhou) Co., Ltd. 莱杰生物科技（苏州）有限公司