



# 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:** Deep Well Plate

**Models:** DWPR20U; DWPR20V; DWPS09V; DWPC96; DWPS20IU;  
DWPC8V; DWPC8VC; DWPC8RC;

**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

