CE

DECLARATION OF CONFORMITY

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

Manufacturer:	Zhejiang Concern Biological Technology Co., Ltd
Address:	2F Building 2, 48 Dongshan Road, Jiangdong Sub-district, Yiwu, Zhejiang, China
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name:	Vacuum Blood Collection Tubes
Specification:	Plain tube, Pro-coagulation tube, Gel& Clot activator tube, Glucose tube, PT tube, Heparin Lithium tube, Heparin Sodium tube, EDTA K2/K3 tube, ESR tube
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: 2016

EN ISO 20417: 2021

Signature: _____

Position: Director

Date: 2022.1.19

Place: Zhejiang / China