



DECLARATION OF CONFORMITY

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

Manufacturer: Shijiazhuang Kang Weishi Medical Instrument Co., Ltd
Address: No.95.Yuanshi Street, Yuanshi County, Shijiazhuang
City, Hebei Province, China.
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam,
Netherlands
Product Name: Blood collection tube
Specification: ST-II
Classification: Others (IVDD)
**Conformity Assessment
Procedure:** Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2012

EN ISO 18113-3:2011

EN ISO 18113-1:2011

*On behalf of SUNGO Europe office, I confirmed we are
EU REP of the company who issue this document.*

Signature:

Date:

2020. 11. 25



Authorized Signature (S)



DECLARATION OF CONFORMITY

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

Manufacturer: Shijiazhuang Kang Weishi Medical Instrument Co., Ltd
Address: No.95.Yuanshi Street, Yuanshi County, Shijiazhuang
City, Hebei Province, China.
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam,
Netherlands

Product Name: Disposable Virus Sampling Tube
Specification: ST-II

Classification: Others (IVDD)
**Conformity Assessment
Procedure:** Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2012

EN ISO 18113-3:2011

EN ISO 18113-1:2011

*On behalf of SUNGO Europe office, I confirmed we are
EU REP of the company who issue this document.*

Signature: 王松岩



Wang Songyan

Date: 2020-11-19

Authorized Signature (S)

