

EU Declaration of Conformity

according to the DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

On the basis of the referenced test report(s), sample(s) tested of the below product have been found to comply with the standards harmonized with the directives listed on this verification at the time the tests were carried out. Other standards and Directives may be relevant to the product. This verification is part of the full test report(s) and should be read in conjunction with it <them>.

the medical device(s))	Manufacturer:	Wuhan Servicebio Technology Co., Ltd.
	Address:	RM502(Y),22th Building, Wuhan Guanggu international Biological medicine company accelerator 1-2 phase,388th Gaoxin second road, East Lake High-Tech Developing Zone, Wuhan, China
	Single Registration Number (SRN) of the Manufacturer:	CN-MF-000011685
	European Representative (ER):	Share Info Consultant Service LLC Repräsentanzbüro
	Address:	Heerdter Lohweg 83, 40549 Düsseldorf
Single Registration Number (SRN) of ER:		DE-AR-000005133
We, the manufacturer, declare under our sole responsibility that:		
	Product Name:	Centrifuge Tube
	Type/model	<i>Refer to the Appendix I for details.</i>
	Intended Purpose:	1) Centrifuge Tube with caps (conical bottom/round bottom) and Centrifuge Tube with screw caps (conical bottom/round bottom/Self-Standing): separation and preparation of various biological samples. 2) 8-strip tube(cap/ row cap)and 12-strip tube(cap/ row cap): batch separation and preparation of various biological samples. 3) Ultrafiltration (conical bottom) centrifuge tube: concentration of microbial samples, purification of samples, desalination, buffer replacement, diafiltration.
	Classification: (ANNEX IX of the IVDD)	Others devices

Conformity assessment procedure: IVDD 98/79/EEC Annex III
Applied harmonized standards and Common Specification: Refer to the Appendix II for details.
Registration No.:

Appendix I: Model of Product

Model

- With cap (conical bottom)
- With cap (round bottom)
- Screw cap (conical bottom)
- Screw cap (round bottom)
- Screw cap (Self-Standing)
- 8-strip tube with cap
- 8-strip tube with row cap
- 12-strip tube with cap
- 12-strip tube with row cap
- Ultrafiltration (cone bottom)

Appendix II: Applied harmonized standards and Common Specification

is/are in conformity with the relevant provisions and requirements of the Council and the parliament DIRECTIVE 98/79/EC for in vitro diagnostic medical device and all applicable harmonized standards and Common Specification. All supporting documents are retained under the premises of the manufacturer.

Applied harmonized standards and Common Specification	IVDD 98/79/EC	MEDDEV 2.7/1 rev.4
	MEDDEV2.12/1-rev.8	EN ISO 14971:2012
	EN ISO 13485:2016	EN 62366-1: 2015
	EN 1041:2008	EN ISO 23640:2015
	EN 13640:2002	BS EN 13612:2016

This DoC is valid from Nov 19, 2021.

Authorized by: Zhao Hongzhou

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Position: General Manager

Rev. 2.0

Signed on: Nov 19, 2021.

Place: Hubei, China