



DECLARATION OF CONFORMITY

ACCORDING TO In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands
SRN: NL-AR-000000247

Device Classification

Classification: Class A.
Rule: According to Rule 5, Annex VIII, of
In Vitro Diagnostic Medical Devices
Regulation (EU)2017/746.

Applicable Standards

EN ISO 20417: 2021.
EN ISO 15223-1:2021.
EN ISO 18113-1:2011.
EN ISO 14971:2019.
EN ISO 18113-3:2011

Remark

*The declaration of conformity is valid in connection
with the release technical document CE/IVDR-
W02069003-01.*

*All the supporting documentation is retained at the
premises of the manufacturer.*

*The Declaration of Conformity is exclusively under
the sole responsibility of the manufacturer.*

Manufacturer

Name: Shandong Baiou Medical Technology Co.. LTD
Address:Room 103. Building 4. Zone 3. Times
Headquarters Base. No. 15 Lanxiang Road. Tianqiao
District. Jinan City. Shandong Province
SRN: /

Product Information

Name: CENTRIFUGE
Model: Annex I
EMDN: W02069003
Basic UDI-DI: /
Classification: Class A

Conformity Assessment

Compliance of the designated product with the In Vitro
Diagnostic Medical Devices Regulation (EU)2017/746
has been assessed by issuing the EU declaration of
conformity referred to in Article 17 after drawing up the
technical documentation set out in Annexes II and III.

Declaration

We herewith declare that the above-mentioned
products meet the requirements of In Vitro Diagnostic
Medical Devices Regulation (EU) 2017/746 and the
applicable standards above.

Signature:  Date: 2023.12.18

Position: GM Place: Shandong/China

Annex I

Name	Model
CENTRIFUGE	<p>TDL-600A、DL-1000C、TDL-200、TDL-280、TDL-320、TDL-350、TDL-360、TDL-400、 TDL-420、TDL-450、TDL-5000、TDL-360C、TDL-400C、TDL-500C、TDL-600C、TDL-36B、 TDL-mini6K、TDL-mini10K、TDL-32B、 TDL-30B、TDL-40B、TDL-530、TDL-12C、 TDL-12K、TDL-24K、TDL-40C、SW-40、SW-60、SW-80、SW-100、SW-150、TGL-12MX、 TGL-16A、TGL-18A、TGL-20A、TGL-16、 TGL-18、TGL-20、TGL-10、TDL-220R、 TDL-320R、TDL-360R、TDL-400R、TDL-420R、TDL-450R、DL-5000R、DL-4000R、 DL-6000R、DL-8000R、TGL-10R、TGL-12R、TGL-14R、 TGL-16RC、TGL-16R、TGL-18R、TGL-20R、 TGL-21R、GL-20R、GL-21R、GL-25R H5424、H5427、H5430、H5702、H5804、H5810、H5910、H5920、L5024、L5048、L5056、 L4064、L4068、L4096、L5096、L5098、L6200、L6400、L5024R、L5048R、L5056R、L4064R、 L4068R、L4096R、L5096R、L5098R、L6000R、L6100R、H5424R、H5427R、H5430R、 H5702R、H5804R、H5810R、H5910R、H5920R、L6200R、L6400R、L6600R、L6800R、 L8200R、L8400R、L8600R、L8800R</p>