



DECLARATION OF CONFORMITY

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

EU Representative

SUNGO Cert Gmbh
Harffstr. 47,40591 Düsseldorf, Germany
SRN: DE-AR-000010869

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 15223-1:2016,
EN ISO 18113-1:2011,
EN ISO 14971:2019

Remark

*The declaration of conformity is valid in connection
with the release technical document
CE/IVDR-CT-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: Shaoxing Shangyu Mingji Plastic Co.,Ltd.
Address: Shengqiao, Xiaoyue, Shangyu, Shaoxing,
Zhejiang, China 312367

Product Information

Name: Centrifuge Tube

Model: See annex

GMDN: 58970

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: *Song yiping* Date: 2021.8.19

Position: GM Place: Shaoxing/China



Annex

Product Name	Model	GMDN	Basic UDI-DI
Centrifuge Tube	MCTB005, MCTB015, MCTB020, MCTBS015, MCS005, MCS015, MCS020, MCT012, MSC001, CTB05-20, CTBF05-20, CTBS05-20, CTB10-10, CTB12-10, CTB15-25, CTB50-25, CTFS50-25, CTF15-25, CTF50-25, CTR15-25, CTR50-25, CTF05-50	58970	/

