



# 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-PT-02.*

*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:** PIPET TIP  
**Model:** See annex  
**GMDN:** 16822  
**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: CM

Place: Shaoxing/China

Product Name	Model	GMDN	Basic UDI-DI
<b>PIPET TIP</b>	MTBS10-10, MTB10-10, MTB200-10, MTB200L-10, MTB300-10, MTB300L-10, MTB1000-10, MTB1250-10, MTB5000-10D, MTB5000-10T, MTB10000-10D, MTB10000-10T, MTRS10-96, MTR10-96, MTR200-96, MTR200L-96, MTR300-96, MTR300L-96, MTR1000-96, MTR1250-96, MTR5000-24, MTR5000-40, MTR10000-24D, MTR10000-24T, MRS10, MR10, MR200, MRL200, MR300, MRL300, MR1000, MR1250, MTBS10-10L, MTB10-10L, MTB200-10L, MTB200L-10L, MTB300-10L, MTB300L-10L, MTB1000-10L, MTB1250-10L, MTRS10-96L, MTR10-96L, MTR200-96L, MTR200L-96L, MTR300-96L, MTR300L-96L, MTR1000-96L, MTR1250-96L, MRS10L, MR10L, MR200L, MRL200L, MR300L, MRL300L, MR1000L, MR1250L, MFTBS10-10, MFTB10-10, MFTB20-10, MFTB50-10, MFTB100-10, MFTB200-10, MFTB200L-10, MFTB300-10, MFTB1000-10, MFTB1250-10, MFTB5000-10D, MFTB5000-10T, MFTB10000-10D, MFTB10000-10T, MFTRS10-96, MFTR10-96, MFTR20-96, MFTR50-96, MFTR100-96, MFTR200-96, MFTR200L-96, MFTR300-96, MFTR1000-96, MFTR1250-96, MFTR5000-24, MFTR5000-40, MFTR10000-24D, MFTR10000-24T, MFTBS10-10L, MFTB10-10L, MFTB20-10L, MFTB50-10L, MFTB100-10L, MFTB200-10L, MFTB200L-10L, MFTB300-10L, MFTB1000-10L, MFTB1250-10L, MFTRS10-96L, MFTR10-96L, MFTR20-96L, MFTR50-96L, MFTR100-96L, MFTR200-96L, MFTR200L-96L, MFTR300-96L, MFTR1000-96L, MFTR1250-96L, MACT050-T, MACT200-T, MACT1000-T, MACF050-T, MACF200-T, MACF1000-T, MACT050-H, MACT200-H, MACT1000-H, MACF050-H, MACF200-H, MACF1000-H	16822	/