



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

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

## Conformity Assessment

### Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

### Applicable Standards

EN ISO 14971: 2019  
EN ISO 15223-1: 2021  
EN ISO 20417:2021  
EN ISO 10993-1: 2020  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2023  
EN ISO 10993-23: 2021

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-L150201-01.*

*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:** Tangshan Zhengtong Exhibition Co., Ltd.

**Address:** No.24 Chaoyang Road, Lubei District, Tangshan City, Hebei Province, China

**SRN:** CN-MF-000018452

## Product Information

**Name:** Cheek Retractor

**Model:** Spandex Lip Retractors; Mirahold Cheek Retractors; Cheek Retractors; Split Type Mouth Support (Child, Adult)

**EMDN:** L150201

**Basic UDI-DI:** 697124139DCC00015K

**Classification:** Class I, According to Rule 5, Annex VIII, Regulation (EU) 2017/745

## Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:

Date: 2024.9.23

Position: GM

Place: Tangshan/China

