DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Name: SUNGO Cert Gmbh

Address: Harffstr. 47,40591 Düsseldorf, Germany

SRN: DE-AR-000010869

Manufacturer

Name: TANGSHAN ZHENGTONG EXHIBITION CO., LTD.

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

SRN: CN-MF-000018452

Conformity Assessment

Conformity Assessment Procedure

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

Applicable Standards

EN ISO 14971: 2019/A11:2021

EN ISO 15223-1:2021/A1:2025

EN ISO 20417:2021

EN ISO 10993-1: 2025

EN ISO 10993-5: 2009/A11:2025

EN ISO 10993-10: 2023

EN ISO 10993-23: 2021/A1:2025

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 ofthe manufacturer.

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

File No.: CE/MDR- L150201-01-08

Ver: B/0

Product Information

Name: Cheek Retractor

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

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 2026.7.1

Position: GM Place: Tangshan/China