



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

