



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.  
Olympisch Stadion 24, 1076DE  
Amsterdam, Netherlands  
SRN: NL-AR-000000247

## 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: 2013

### Remark

*The declaration of conformity is valid in connection with the release technical document CEMDR-Q0199-01.*

*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: NANCHANG DENTAL BRIGHT  
TECHNOLOGY CO.,LTD  
Address: Building 182, Nanchang Jiahai Industrial  
Park, No.2799 Tianxiang Blvd, Gaoxin Dist.,  
Nanchang, Jiangxi Prov., China

## Product Information

Name: TEETH WHITENING STRIPS  
Model: GS-003N, GS-003B, GS-003D, GS-003R, GS-003P,  
GS-003H, GS-003C  
EMDN: Q0199  
Basic UDI-DI: /  
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: 2022.2.15

Position: GM

Place: Nanchang/China

