



# 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

### Applicable Standards

EN ISO14971:2019  
EN ISO15223-1:2016  
ISO10993-1:2018  
EN ISO10993-5:2009  
EN ISO10993-10:2010  
EN 1041:2008+A1:2013  
EN 62366-1:2015

### Remark

The declaration of conformity is valid in connection  
with the release technical document  
[CE/MDR-TRIBEST18](#).

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: TRIBEST DENTAL PRODUCTS CO., LTD.  
Address: NO.98 ZHONGLING ROAD,SANMAO  
STREET,YANGZHONG,ZHENJIANG,JIANGSU,CHINA

## Product Information

Name: Dental Tray  
Model: 12-10001~ 12-10020  
GMDN: 16350  
Basic UDI-DI: 69748153712-10001PW  
Classification: Class I

*On behalf of SUNGO Europe office, I confirmed we are  
EU REP of the company who issue this document.*



## Declaration

*Authorized Signature (S)*

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: Mar 1<sup>st</sup>,2021

Position: General Manager

Place: Yangzhong

*Zhou Jiahong*

