



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-TRIBEST12](#).

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: Prophy Brush and Cup
Model: 15-10001 ~ 10050, 15-30001 ~ 30050
GMDN: 64015&46938
Basic UDI-DI: 69748153715-30050SL
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 18th, 2021

Zhou Jiahong

Position: General Manager

Place: Yangzhong