



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

Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745.

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-TRIBEST10.

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
SRN: CN-MF-000027307

Product Information

Name: Sterilization pouches and reels
Model: 11-50001 ~ 11-50083
GMDN: 13735
Basic UDI-DI: 69748153711-50043R9
Classification: Class I

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

Declaration

Sungo

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 1st, 2021

Position: General Manager Place: Yangzhong