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-TRIBEST13.

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: Barrier Film and Sleeves
Model: Plastic sleeves(11-30004 ~ 11-30115); Barrier film(11-30001 ~30002)
GMDN: 12535
Basic UDI-DI: 69748153711–30035QL
Classification: Class I

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

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Authorized Signature (S)

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:Feb 9th,2021

Zhou Jianhong

Position:General Manager Place:Yangzhong