



**EC Declaration of Conformity**



**Regarding Medical Device Regulation(2017/745)**

**Manufacturer**

Name: Nanchang Dental Bright Technology Co.,Ltd.

Address: Building 182, Jiahai Industrial Park, No. 2799, Tianxiang Avenue, High-Tech Zone, Nanchang, Jiangxi, China

**European Authorized Representative:**

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

**Product**

Name: Mouth Tray

Classification: I

Rule: Rule 5, Annex VIII, EU Medical Device Regulation (2017/745)

Conformity assessment procedure: Annex II+III

We confirm our product meets the requirements of Medical Device Regulation and the following harmonized standards.

EN ISO 14971:2012, EN ISO 15223-1:2016, IEC62366-1:2015, EN 1041:2008, ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2010

Signature: *Justin Qin*

Position: *Manager*



Date: *2020.01.21*

*On behalf of SUNGO Europe office, I confirm that the product meets the requirements of EU MDR of the company who issues this document.*



*Justin Qin*