



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 confirmed as the EU REP of the company who issue this declaration.



Justin Qin

Authorized Signature



File No: DB/MDR-03-02, Rev A/0



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: Teeth Whitening Gel

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 1041:2006, 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 confirmed we are EU REP of the company who issue this document.



Authorized Signature (S)

CS

扫描全能王 创建

File No: DB/MDR-01-02, Rev A/0



EC Declaration of Conformity



Regarding Medical Device Regulation(2017/745)

Manufacturer

Name: Nanchang Dental Bright Technology Co.,Ltd.
Address: Building 162, 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: Teeth Whitening Kit
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 confirmed we are EU REP of the company who issue this document.



Authorized Signature (S)

File No: DB/MDR-02-02, Rev A/0



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: Teeth Whitening light
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 confirmed we are EU REP of the company who issue this document.



Justin Qin

Authorized Signature (S)