



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 the EU MDR of the regulation, also from this date.



Justin Qin

Authorized Signatory





EC Declaration of Conformity



Regarding Medical Device Regulation(2017/745)

Manufacturer

Name: Nanchang Dental Bright Technology Co., Ltd.
Address: Building 162, Jialai Industrial Park, No. 2796, Tiesheng Avenue, High-Tech Zone, Nanchang, Jiangxi, China

European Authorized Representative:

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1078DE Amsterdam, Netherlands

Product

Name: Teeth Whitening Gel
Classification: I
Rule: Rule 0, Annex VII, EU Medical Device Regulation (2017/745)
Conformity assessment procedure: Annex II-B

We declare our product meets the requirements of Medical Device Regulation and the following harmonized standards:

EN ISO 14971:2012, EN ISO 13023-1:2016, ISO 22868-1:2013, EN 1041:2006, ISO 10993-1:2016, EN ISO 10993-5:2009, EN ISO 10993-10:2010

Signature: *Justin Qin*

Position: *Manager*

Date: *2020.07.27*



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



Justin Qin

Authorized Signature

File No: DBMDH-01-02, Rev A0



EC Declaration of Conformity



Regarding Medical Device Regulation(2017/745)

Manufacturer

Name: Hanchang Dental Bright Technology Co., Ltd.
Address: Building 162, Jialu Industrial Park, No. 2798, Tiansheng Avenue, High-Tech Zone, Nanchang, Jiangxi, China

European Authorized Representative:

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1570CE Amstelveen, Netherlands

Product

Name: Teeth Whitening Kit
Classification: I
Rule: Rule 5, Annex VIII, EU Medical Device Regulation (2017/745)
Conformity assessment procedure: Annex I+II

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, IEC60601-1:2015, EN 1041:2006, ISO 10993-1:2016, EN ISO 10993-5:2006, EN ISO 10993-10:2010

Signature: *Justin Ooi*

Position: *Manager*



Date: *2021.07.21*

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

Justin Ooi

Authorized Signature

File No: D8/MOH-02-02, Rev A10



EC Declaration of Conformity



Regarding Medical Device Regulation(2017/745)

Manufacturer

Name: Nanjing Deme Bright Technology Co., Ltd.
Address: Building 102, Jiahai Industrial Park, No. 2793, Tianzhang Avenue, High-Tech Zone, Nanjing, Jiangsu, China

European Authorized Representative:

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 107006 Amsterdam, Netherlands

Product

Name: Tooth Whitening light
Classification: I
Rule: Rule E, Annex VIII, (EU Medical Device Regulation (2017/745))
Conformity assessment procedure: Annex B(II)

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

EN ISO 14971:2013, EN ISO 18233-1:2016, IEC62366-1:2015, EN 1041:2009, ISO 10993-1:2016, EN ISO 10993-5:2009, EN ISO 10993-12:2012

Signature: *Justin Ou*

Position: *Manager*



Date: *July, 2021*

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



Justin Ou

Authorized Signature (S)