



Compliance Report

Applicant: Nanchang Dental Bright Technology Co., Ltd.
Address: Building 182 Jiahai Industrial Park, High-Tech Development Zone, Nanchang, Jiangxi Province, China.
Product: Teeth Whitening Kit (Smart Teeth Whitening Kit, Smart Teeth Whitening Device Kit, Teeth Whitening Light Kit, The Professional Whitening Kit, Teeth Whitening Home Kit), Teeth Whitening Strips, Teeth Wipe, Teeth Whitening Gel, Desensitizing Gel, Dental Gum Dam, Dual Barrel Syringe Teeth Whitening Gel, Anti-snoring Mouth Tray, Anti-snoring Band, Mouth Spray, Teeth Whitening LED Light, Teeth Whitening Foam, Vitamin E Swab, Cheek Retractor, Dental Brace, Teeth Whitening Mouth Tray, Dental Impression Material (Si-Impression Material), Denture Adhesive, Mouth Tray Case, Teeth Whitening Powder, Charcoal Teeth Whitening Powder, Coconut oil pulling, Coconut oil sachet
Type: See annex for details
Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 02719

Initial Issue Date: 18 May 2017

General Manager (Signature)



Annex to Report (No. 02719)

Nanchang Dental Bright Technology Co., Ltd.

Product Name	Type
Teeth Whitening Strips	YT-01, YT-02
Teeth Wipe	YC-01
Teeth Whitening Gel	Syringe: 1.2ml/ 3ml/ 5ml/ 10ml Pen: 2ml/ 4ml
Desensitizing Gel	Syringe: 1.2ml/ 3ml/ 5ml Pen: 2ml/ 4ml
Dental Gum Dam	Syringe: 1.2ml/ 1.5ml/ 2.2ml
Dual Barrel Syringe Teeth Whitening Gel	2.5ml (DG-2.5) / 5ml(DG-5)
Anti-snoring mouth tray	ZHT-01
Anti-snoring band	ZHD-01
Mouth Spray	2ml(MS-2) / 5ml(MS-5) / 8ml(MS-8)
Teeth Whitening LED Light	1led, 5leds
Teeth Whitening Foam	MBF-01
Vitamin E Swab	VES-01
Cheek Retractor	Type C, Type O, Type W
Dental Brace	TE-4
Teeth Whitening Mouth Tray	TE-01, TE-02, TE-03, TPT-01, TPT-02, TPT-03, TPT-04
Dental impression material (Si-Impression Material)	YMC-01

This annex is only valid if attached to the report mentioned above.



Annex to Report (No. 02719)

Nanchang Dental Bright Technology Co., Ltd.

Product Name	Type
Denture Adhesive	JYN-01
Mouth Tray Case	YTC-01, YTC-02, YTC-03, YTC-04
Teeth Whitening Powder	DB-WP01, DB-WP02
Charcoal Teeth Whitening Powder	DB-CWP01, DB-CWP02
Coconut oil pulling, Coconut oil sachet	DB-CO01
Teeth Whitening Kit (Smart Teeth Whitening Kit, Smart Teeth Whitening Device Kit, Teeth Whitening Light Kit, The Professional Whitening Kit, Teeth Whitening Home Kit)	HK08, HK06, custom-made

This annex is only valid if attached to the report mentioned above.