



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 Darn, 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, Check Retractor, Dental Brace, Teeth Whitening Mouth Tray, Dental Impression Material (Si-Impression Material), Denture Adhesive, Mouth Tray Case.
Type: See annex for details
Product Class I

Classification:

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. 02598

Initial Issue Date: 01 Sep 2016

Tony Chen

General Manager (Signature)

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Annex to Report (No. 02598)

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	2.5m (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
Denture Adhesive	JYN-01
Mouth Tray Case	YTC-01, YTC-02, YTC-03, YTC-04
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.

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