



DECLARATION OF CONFORMITY



Name and address of manufacturer: BDC Dental Corporation Ltd.
Part 3, No. 1 Guanchong Section,
Shilian Rd., Shiqi Town, Panyu District,
Guangzhou, 511450, China

declare on our own responsibility that
the medical device: Procedure Face Mask (nonsterile), Sugical Mask (nonsterile)
Modle: II, IIR
Type/Specification:
Type:IIR
Specification:170*95mm,155*105mm

meets all applicable requirements of the Directive 93/42/EEC Annex I, as amended by Directive 2007/47/EC

Applied standards : EN 14683:2019 Medical face masks-Requirements and test methods

Classification: Classified as class I not sterile according to Annex IX, rule 1 of the Directive 93/42/EEC.

Conformity assessment procedure: Conformity assessment was performed according to Annex V II of the Directive 93/42/EEC.

The Authorized Representative within the EU who
has been empowered to enter into commitments
on our behalf is: Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd,
2595AA, The Hague, Netherlands.

2021-05-28

Validity period

2020-05-28
Guangzhou

place, date

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Name: Mr. HUA YANG
Function: Management Representative
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