

DECLARATION OF CONFORM

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), Surgical 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

上加清原

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

Dental Corporation Name: Mr. HUA YANG

Function: Management Representative