

Zhejiang Gongdong Medical Technology Co.,Ltd.

No.10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang,  
People's Republic of China.  
http://www.chinagongdong.com



CE TechFile

CE-007-04

### *Declaration of Conformity*

Manufacturer: Zhejiang Gongdong Medical Technology Co.,Ltd.  
Beicheng Industrial Area 318020 Huangyan China

European Representative: Shanghai International Holding corp.GmbH(Europe)  
Eiffestrate 80 20537 Hamburg Germany

Product Name: Disposable Sterile Swabs

Model: male swab, female swab, mouth and nasopharyngeal type swab (also known as viral sampling swab), and For Anus Swab,

UMDNS Code: 13914

Classification (MDD, Annex IX): I sterile, rule 5

Conformity Assessment Route: MDD93/42EEC Annex: V.3

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. Zhejiang Gongdong Medical Technology Co.,Ltd. is exclusively responsible for the DoC.

### DIRECTIVES

#### General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC),

All applicable harmonized Standards

Notified Body: TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65 • 80339 München Germany

Identification number: CE0123

(EC) Certificate(s): G2S 042464 0034 Rev.00

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2020-06-05

Place, Date of Issue: HuangYan

Place, Date of Issue: HuangYan 2019-12-01

Signature:

Name:

Position:

5.1.2e

Position:

Rev. C