

Declaration of Conformity

MANUFACTURER:

Bonree Medical Co., Ltd.

Address: 1st floor of Building No.2 Building No.4, Longzhu Village Economic Estate Longzhu Avenue
Nanlang 528451 Zhongshan, Guangdong PEOPLE'S REPUBLIC OF CHINA

AUTHORIZED EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffeustraße 80, 20537 Hamburg, GERMANY

MEDICAL DEVICE:

Model Name: Laryngeal Masks Devices

Type: PVC laryngeal mask Device

Ref No.: 23201002; 23202002; 23203002; 23204002; 23205002; 23206002; 23207002;

Size: 1, 1½, 2, 2½, 3, 4, 5

Classification: IIa (Rule 5, Annex IX, MDD 93/42/EEC (2007))

UMDNS code: 17986

Conformity Assessment Procedure: Annex V

We herewith declare in our own responsibility that the above-mentioned product(s) meet(s) the provisions of the Council Directive 93/42/EEC of 14th June 1993 concerning medical devices, amended by Council Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer (head of Quality department).

General applicable directives: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning Medical devices, amended by Council Directive 2007/47/EC.

Referenced standard(s): EN ISO 13485:2016/ EN ISO 14971:2019/ EN ISO 11135:2014/
EN ISO 15223-1:2021/ EN ISO 20417:2021/ EN 15986:2011/ EN ISO 11737-1:2018/A1:2021
EN556-1:2001/AC:2006/ EN ISO 11737-2:2020/ EN ISO 11607-1:2020/A11:2022/
EN ISO 11607-2:2020/A11:2022/ EN ISO 10993-1:2020/ EN ISO 10993-5:2009/ EN ISO 10993-10:2013/
EN ISO 10993-7:2008/AC:2022/ EN ISO 11138-1:2017/ EN ISO 11138-2:2017 /ENISO 11138-3:2017/
EN 62366-1:2015/A1:2020/ EN ISO 15001:2011/ EN ISO 14155:2020/ EN ISO 14644-1:2015

Notified Body: TÜV SÜD Product Service GmbH

Address: Zertifizierstelle, Ridlerstraße 65, 80339 München, Germany.

Identification No.: 0123

EC Certificate(s) : G2 094928 0004 Rev. 03

EC certificate(s) valid until: 2024-05-26

Person keeping the technical documentation: He Hongbo
1st floor of Building No.2 Building No.4, Longzhu Village
Economic Estate Longzhu Avenue
Nanlang 528451 Zhongshan, Guangdong PEOPLE'S
REPUBLIC OF CHINA / 2023.12.01
(Place and date of issue of this certificate)*



Management Representative
(Signature and title of authorized person)*