

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 REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestraße 80, 20537 Hamburg, GERMANY

MEDICAL DEVICE:

Model Name: Tracheostomy Tubes

Type: Cuffed, Uncuffed

Ref No.: 222 30 00 2;222 35 00 2;222 40 00 2;222 45 00 2;222 50 00 2;222 55 00 2;222 60 00 2;222 65 00
2;222 70 00 2;222 75 00 2;222 80 00 2;222 85 00 2;222 90 00 2;222 95 00 2;222 10 00 2; 223 30 00 2;223 35
00 2;223 40 00 2;223 45 00 2;223 50 00 2;223 55 00 2;223 60 00 2;223 65 00 2;223 70 00 2;223 75 00 2;223
80 00 2;223 85 00 2;223 90 00 2;223 95 00 2;223 10 00 2;

Size: I.D.3.0, I.D.3.5, I.D.4.0, I.D.4.5, I.D.5.0, I.D.5.5, I.D.6.0, I.D.6.5, I.D.7.0, I.D.7.5, I.D.8.0,
I.D.8.5, I.D.9.0, I.D.9.5, I.D.10.0

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

UMDNS code: 14094

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 10993-3:2014/ EN ISO 10993-4:2017/
EN ISO 10993-5:2009/ EN ISO 10993-6:2016/ EN ISO 10993-10:2013/ EN ISO 10993-7:2008/AC:2022/
EN ISO 10993-11:2018/ EN ISO 11138-1:2017/ EN ISO 11138-2:2017 /EN ISO 11138-3:2017/
EN ISO 14155:2020/ EN ISO 14644-1:2015/ EN ISO 5366:2016/ EN 62366-1:2015/A1:2020

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)*