

Declaration of Conformity

MANUFACTURER:

Bonree Medical Co., Ltd.

Address: No.4 Longzhu Garden, Wanmu Industrial Estate, Nanlang 528451, Zhongshan, Guangdong,
PEOPLE' REPUBLIC OF CHINA

AUTHORIZED EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffeustraße 80, 20537 Hamburg, GERMANY

MEDICAL DEVICE:

Model Name: Yankauer Suction Sets (Brand name: )

Size: Set, Suction connecting tube (9/32", 1/4", 3/16"), Yankauer handle

Classification: IIa (Rule 7, Annex IX, MDD 93/42/EEC)

UMDNS code: 16779

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):

ISO13485:2016/ISO14971:2007/ISO11135:2014/EN980:2008/EN1041:2008/ISO11737-1:2006/ISO11737-2:2009/ISO11607-1:2006/ISO11607-2:2006/ISO10993-1:2009/ISO10993-5:2009/ISO10993-10:2010/ISO10993-7:2008/ISO14155:2011/ISO11138-1:2017/ISO11138-2:2017/ISO11138-3:2017.

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

No.4 Longzhu Garden, Wanmu Industrial Estate,

Nanlang 528451, Zhongshan, Guangdong,

PEOPLE' REPUBLIC OF CHINA/2015.12.06

(Place and date of issue of this certificate)*



(Signature and title of authorized person)*