

## 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: EiffestraÙe 80,20537 Hamburg, GERMANY

### **MEDICAL DEVICE:**

**Model Name:** Laryngeal Masks Devices (Brand name:  )

**Type:** PVC laryngeal mask Device

Silicone laryngeal mask Devices single use

Reusable silicone laryngeal mask Devices

**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):**

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)\*