

# Declaration of Conformity

**Manufacturer:**

Guangdong Taibao Medical Science And Technology Co., Ltd.  
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**European Representative:**

Shanghai International Holding Corp. GmbH (Europe)  
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**Product Name:**

Surgical Mask (Model: Non-sterile 17.5cm×9.5cm)

**Classification (MDD, Annex IX):** I, rule 1

**Conformity Assessment Route:** Annex VII of Directive 93/42/EEC

We herewith declare that the above mentioned products meet the transposition into national laws, the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer.

**General applicable directives:**

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

**Standard Applied:**

EN ISO 15223-1:2016 EN 1041:2008/A1:2013 EN ISO 10993-1:2009/AC: 2010  
EN ISO 10993-10:2010 EN ISO 13485:2016 EN ISO 14971:2012 EN 14683:2019  
EN ISO 14698-1:2003 EN ISO 14698-2:2003 EN ISO 14644-3: 2019  
EN ISO 14644-1:2015 EN ISO 14644-2:2015 EN 62366-1-2015/AC:2015  
EN ISO 11607-1:2017 EN ISO 11607-2:2017 EN ISO 11737-1:2018

**First start of CE-MARK:** Mar. 19, 2020

**Signature:** Managing Director



**Place, Date of Issue:** Puning, Mar. 19, 2020

