

## EC-Declaration of Conformity

Document No. DOC-AY-20210301-V1

**Manufacturer:** Changzhou Aoyang Textile Co., Ltd.  
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District, Changzhou, 213119, Jiangsu, China

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**Competent Authority:** Ministerio Sanidad y Consumo Agencia Española  
de Medicamentos y Productos Sanitarios

**Product:** Disposable medical face mask

**Type:** EN 14683:2019 Type I/Type IIR

Classification: Class I, According to Rule 1, Annex IX of MDD 93/42/EEC as amended by Directive 2007/47/EC

### **Harmonized Standards:**

EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008,  
EN 14683:2019+AC:2019 EN ISO 10993-1:2009/AC:2010,  
EN ISO 10993-5:2009, ISO 10993-10:2010

**Conformity Assessment Route:** Annex VII of Directive 93/42/EEC as amended by 2007/47/EC.

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Year of CE marking: 2021

Signed for and on behalf of:

Company: Changzhou Aoyang Textile Co., Ltd.

General Manager: Jianmin Song

Signature : Jianmin Song

Place & Date: Changzhou City, 4 th March, 2021

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