

# CE Documentation Review



No. OP200324S.TBH0D90

**Holder:** Yangzhou Yangsheng Medical  
Science & Technology Co., Ltd  
Yada Road TouQiao Village Yangzhou City

**Review goal:** Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

**Product:** Disposable medical mask (Not Sterile)  
**Model(s):** 170mm\*95mm, 140mm\*90mm

**Classification:** Class I (Not Sterile)  
(accordingly to the Manufacturer's declaration)

**Review output:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices.  
Technical documentation identified with the no. TMAH20031523009 dated 24 March 2020.  
The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01\_ECM rev.3 available at: [www.entecerma.it](http://www.entecerma.it)

Date of issue 24 March 2020

Approver  
ECM Service Director  
Luca Bedonni



Expiry date 23 March 2025

Technical Expert  
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**Ente Certificazione Macchine**

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