

# CE Documentation Review



No. OP200331E.JKH00020

**Holder:** Jiangyin kangyitai health technology  
co. LTD  
No. 53, gubeiyi village, gushan town, jiangyin city,  
jiangsu province

**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):** 17.5cmX9.5cm

**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.  
dated  
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 31 March 2020

Approver  
ECM Service Director  
Luca Redonni



Expiry date 30 March 2025

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**Ente Certificazione Macchine**

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