

# CE Documentation Review



No. 4M200406T.PSF0012

**Holder:** PUTIAN SHUANGMEI FOOTWEAR CO., LTD.  
DUOTOU VILLAGE, SANJIANGKOU TOWN,  
HANJIANG DISTRICT, PUTIAN CITY, FUJIAN, CHINA

**Manufacturer:** PUTIAN SHUANGMEI FOOTWEAR CO., LTD.  
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HANJIANG DISTRICT, PUTIAN CITY, FUJIAN, CHINA

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

**Product:** Medical disposable mask (Not Sterile)

**Model(s):** SL-001, SL-00X, KN95-001, KN95-00X

**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 n. BTS-2290M.  
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)

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