

CE Documentation Review



No. 3Q200329B.SMI0027

Holder: SHENZHEN MAXSHARER IMPORT AND EXPORT CO.,LTD
East No.4 Building, ZhaoFuDa Industry Park,
SongGang BaoAn District, Shenzhen 518105

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): C0603, C0601, C0602, C0604

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. 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

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Approver
ECM Service Director
Luca Bedonni



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Technical Expert
Amanda Payne

