

CE Documentation Review



No. OP200316.ZGMUT90

Holder: Zhongshan Guangyuan Medical Instruments Technology Co., Ltd.
2nd Building, NO.15 ,Taichang Road, Jixi, Xiaolan Town,Zhongshan City .

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Medical Care Mask (**no sterile**)
Model(s): Type I Medical Face Masks; Type II Medical Face Masks; Medical Care Mask

Classification: Class I (no sterile)
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Technical File identified with the no. **TMBJ20031222322**.
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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Reviewer
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