

# CE Documentation Review



No. OB200312.ZFM0N74

**Holder:** Zhongshan First Mountain Electrical Appliance Company Limited

No.31 Hesui Industrial Blvd Suicheng Village, Dongfeng Town, Zhongshan, Guangdong Province, China

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

**Product:** Disposable medical masks (Non sterile)

**Model(s):** F001

**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. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

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