

CE Documentation Review



No. 0H200325M.ANC0270

Holder:	Anhui Newtoshi Cleaning Products Co., Ltd. Industrial Park of Zhongxiao, Wanshou Town, Tianchang City, Anhui Province, China
Review goal:	Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII
Product:	Disposable Medical Face Mask (Not Sterile)
Model(s):	17.5 cm x 9.5 cm, 14.5 cm x 9.5 cm, 12.5 cm x 8.5 cm 3 LAYERS 95% FILTER
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

**Ente Certificazione Macchine**

Via Cà Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy

☎ +39.0516705141 📠 +39.0516705156 ✉ info@entecerma.it 🌐 www.entecerma.it