

# CE Documentation Review



No. 0H200314.XMTUU93

Holder: **Xianxingyu (Jiangsu) Medical Technology Co., Ltd.**

The 2nd Floor, B5 Block, Science And Technology Industrial Park, Hutang, Wujin District, Changzhou, Jiangsu

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

Product: **Surgical mask (no sterile)**  
 Model(s): Flat ear type, Flat strap type, Stereoscopic folding (KN95)

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. Test Report identified with the no. **XMT0202001040LY/MDD**.  
 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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Reviewer  
 Technical expert  
 Amanda Payne

Approver  
 ECM Service Director  
 Luca Bedonno

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