

CE Documentation Review



No. 4Q200320.XKMUW77

Holder: Xinxiang Kangbeier Medical Technology Co., Ltd.

East of Mancun Industrial Zone, Changyuan County, Xinxiang City, Henan Province, China

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product: Surgical Mask (Not Sterile)
Model(s): Rectangle (17cm*17cm), Cymbiform (21cm*7cm*8.5cm), Arcuation (L, M, S)

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

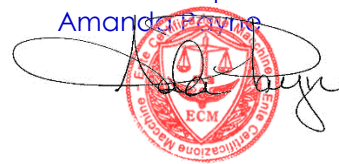
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Approver
ECM Service Director
Luca Bedonni



Technical Expert
Amanda Bionne

**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