

CE Documentation Review



No. OP200401E.ZXM00058

Holder: Zhejiang Xichen Medical Technology Co., Ltd
2nd Floor, 3 Building, 6 Lvyuan Road, Quzhou City, Zhejiang 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): KZ002-1, KZ002-2, KZ004-TYPE1, KZ005-TYPE2, KZ006-TYPE3

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. Technical documentation identified with the no. TMFJ20032623459
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 Redonni



Expiry date 31 March 2025

Technical Expert
Amanda Pavia



Ente Certificazione Macchine