

CE Documentation Review



No. OP200324S.DRM0D95

Holder:	Dongguan Ruikang Medical Supply Technology Co., Ltd No.16, Fudong Henger Road, Tingshan Village, Houjie Town, Dongguan City, Guangdong Province, China; Post Code 523943
Review goal:	Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII
Product:	Disposable Surgical Masks (Not Sterile)
Model(s):	(this certificate certifies only the product without its own specific models)
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. TMGD20031622557 dated 24 March 2020. 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

Date of issue 24 March 2020

Approver
ECM Service Director
Luca Bedonni



Expiry date 23 March 2025

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