Review Report – 审查报告 – 검토 보고서 – Rapport d'Evaluation

CE Documentation Review

No. 3K200403T.GHM0W65

Holder: Guangdong Huojing Medical Device Technology Co., Ltd.
No.139, Qingfeng Road, Qingxi Town, Dongguan City, China

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

Product: KN95 particle respirator (Not Sterile)

Model(s): 2020020325

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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Expiry date 02 April 2025
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