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

Form QAT_10-M06, version 00, effective since March 25th, 2020

CE Documentation Review

No. 0B200404F.HYB0U81

Holder:	Hunan YuanKang Biological Technology Co., Ltd. Heping Team, Sanlian Community, Xidu Town, Hengyang County, Hunan Province, China
Review goal:	Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII
Product:	medical protective mask (Not Sterile)
Model(s):	N95 FFP2, N95-A FFP2, N95-B FFP2, N95-C(childhood)FFP2
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 [illegible] of products. RG01_ECM rev.3 available at: www.entecerma.it

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Approver
ECM Service Director
Luca Redonni

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