

CE Documentation Review



No. 3J2001 HN090

Holder: Hunan Huaihua New Material Technology Co., Ltd.

High-tech Zone, Huaihua City, Hunan Province, China

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Disposable medical masks, medical protective masks (KN95) **(no sterile)**

Model(s): Flat type 175mm x95mm / foldable 15cm x 22cm

Classification: Class I (no sterile)
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

Date of issue 12 March 2020

Expiry date 11 March 2025

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