

CE Documentation Review



No. OP200317.SHCUC18

Holder: Shenzhen Hytera Communications Co., Ltd.

Factory Building No. 1 (3rd floor, 6th floor) , NO. 2 (4th floor, 5th floor) and No. 3, Hytera Technology Industrial Zone, No.3 Baolong 4th Rd.,Baolong Subdistrict, Longgang District, Shenzhen

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

Product: Disposable respirator (**no sterile**)

Model(s): Flat

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. Technical File identified with the no. **TMDDMJ2003123551-AG02-32**.
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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