

CE Documentation Review



No. 0H200323S.WYT0D33

Holder: Wenzhou Yuze Technology Co., Ltd
Taoyuan Road, Xiaojiang town, Pingyang County,
Zhejiang China

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

Product: Face Mask (Not Sterile)
Model(s): YZ-01, YZ-02, YZ-03

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. XMT0201901570S/MDD dated 23 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

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