

# CE Documentation Review



No. 3J200320.ALSUW36

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

**Product:** KN95 Mask, Disposable Planar Mask (Adult), Disposable Planar Mask (Child) **(Not Sterile)**

**Model(s):** KN95 Mask folded size: 15.5\*10.5  
Disposable Planar Mask (Adult) folded size: 17.5\*9.5  
Disposable Planar Mask (Child) folded size: 14.5\*8.5

**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](http://www.entecerma.it)

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