

CE Documentation Review



No. OP200327E.SKM00036

Holder:**Suzhou Keteng Medical Technology Co., Ltd.**

No.555 Beiling Road, Beiqiao Street, Xiangcheng District, Suzhou

Review goal:

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

Product:

Disposable medical mask (Not Sterile)

Model(s):

L, M, S

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. TMSH20031922943

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

Date of issue 27 March 2020

Approver
ECM Service Director
Luca Redonni

Expiry date 26 March 2025

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