

CE Documentation Review



No. 4Q200328R.GFF0088

Holder: Guangdong Fei Fan Mstar
Technology Ltd

A1 workshop, No.10, Dongnan Xincun
Avenue, zone 2, caobian No.3 Industrial Zone,
Dali Town, Nanhai District, Foshan City, China

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

Product: Medical face masks (Not Sterile)

Model(s): N95;KN95;N99;KN99;P3;TYPE II R;TYPE II

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

Date of issue 28 March 2020

Approver
ECM Service Director
Luca Redonni



Expiry date 27 March 2025

Technical Expert
Amanda Payne

