

## Certificate of Compliance



No. 4H200324.SZTD056

Certificate's Holder:

Certification ECM Mark:



Product: Disposable protective mask  
Model(s): 17.5x9.5cm(±0.5cm)-3ply

Verification to: Standard: EN 149:2001+A1:2009

related to CE Directive(s):  
R 2016/425 (Personal Protective Equipment)

**Remark:** This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process. 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)

Issuance date: 24 March 2020

Expiry date: 23 March 2025

Reviewer  
Technical expert  
Amanda Payne

Approver  
ECM Service Director  
Luca Bedonni

Ente Certificazione Macchine Srl

Via Ca' Bella, 243 - Loc. Castello di Serravalle - 40053 Valsamoggia (BO) - ITALY  
☎ +39 051 6705141 📠 +39 051 6705156 📧 info@entecerma.it 🌐 www.entecerma.it

## CE Documentation Review



No. 4H200324.SZTD057

Holder:

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

Product: Disposable protective mask (Not Sterile)  
Model(s): 17.5x9.5cm(±0.5cm)-3ply

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)

Date of issue 24 March 2020

Approver  
ECM Service Director  
Luca Bedonni

Expiry date 23 March 2025

Technical Expert  
Amanda Payne

Ente Certificazione Macchine

Via Ca' Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy  
☎ +39.051.6705141 📠 +39.051.6705156 📧 info@entecerma.it 🌐 www.entecerma.it