

## SCHMIEL 口罩资料信息汇总

1 产品包含 N95,KN95,医用标准和普通防护标准两种 CE 认证

2 N95FDA 认证是普通防护标准： 编号是

Number: 10062992

3 单只塑料袋包装， 照片如下

4 50 只中盒彩盒包装， 尺寸 23\*13\*13CM 照片如下

5 30 盒一箱 尺寸 67x48X42CM



附件是 KN95,N95CE 证书

# CE Documentation Review



No. OP200315.QSMUT48

**Review goal:** Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

**Product:** N95-1860 medical protective mask (**no sterile**)

**Model(s):** Ear-worn

**Classification:** Class I (no sterile)  
(accordingly to the Manufacturer's declaration)

**Review output:** We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the **CE** Marking process. Technical File identified with the no. **TMSD20030922028**.

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)

**Issuance date:** 15 March 2020

**Expiry date:** 14 March 2025

Reviewer  
Technical expert  
Amanda Payne

Approver  
ECM Service Director  
Luca Bedonni



# Certificate of Compliance

No. 0P200315.QSMUT49

Technical Construction File no. TCF-TPMJ2003053564

Certification ECM  
Mark:



Product: KN95 Protective Masks  
Model: Ear-worn

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)

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Reviewer  
Technical expert  
Amanda Payne



Approver  
ECM Service Director  
Luca Bedonni





# Certificate of Compliance

No. 0P200315.QSMUT50

Technical Construction File no. TPSD20030922030

Certification ECM  
Mark:



Product:  
Model:

N95-1860 dustproof protective mask  
Ear-worn

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:



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