

Draft Technical File

Respiratory protection equipment

1. List of Contents
2. Product Description
3. Product Photograph or Drawing
4. Detailed components and materials description
5. End user information (instructions for use, labelling)
 - a. Name and Address of manufacturer.
 - b. Indications for use to which the PPE is designed to protect.
When the reduced testing protocol is used the manufacturer shall include the sentence:
“This filtering half mask is manufactured for COVID-protection only. This filtering half mask is not a PPE device for general use and shall not be used for purposes other than protection against COVID-19.”
 - c. For single use products a warning shall be given that the product shall not be used for more than one shift.
 - d. References to EN149 and type of mask
 - e. CE Mark and NB number for PPE
6. Technical Specifications and productions documents
7. Reference to Standards used
8. Test Reports
9. Declaration of Conformity
10. Notified body contact details