PF1365

EU Commission recommendation 2020/403

Technical File Checklist

Revision 1 (April 2020)

Product Type; RPE / Gloves / Eye protection / Medical clothing
Models covered in this recommendation
Standards/Technical specification used
Category III PPE MODULE C2/D ACTIONS ACTIVITIES
Existing Module C2/D
Mod C2/D Notified Body and certificate number
Copy of last Module C2 audit test/Module D visit report if available
Copy of last NIOSH / ASNZ / GB visit report if available
1. Application form
2. File Contents List
3. Amendment record Sheet
4. Product Description
5. Visual Identification of product either Photograph / Schematics / Drawings
6. Components Details of components / Details of materials
7. Test Reports
8. Declaration of Conformity
9. Marking
Category III PPE products: CE Mark and NB number for PPE. Unless previously approved by NIOSH, NFPA. ASTM, GB or AS/NZS standards- we accept their respective markings. Proposed CE compliamt markings required.
Category II PPE products: CE Mark. Unless previously approved by ANSI, GB or AS/NZS standards- we accept their respective markings.
Type-identifying marking.

PF1365

EU Commission recommendation 2020/403

Technical File Checklist

Revision 1 (April 2020)

10. User Information:
Name and Address of manufacturer.
The risk against which the PPE is designed to protect.
The Information to be supplied by the manufacturer shall include the sentence: "This filtering half mask//protective faceshield//gowns//glove is manufactured for COVID-protection only. This filtering half mask//protective faceshield//gowns//gloves is not a PPE device for general use and shall not be used for purposes other than protection against COVID-19."
For products without cleaning, disinfecting procedure, a warning shall be given that the product shall not be used for more than one shift.
References to Regulation & Technical Specification: **BSI's PPE for Healthcare Professionals 2020/403 – RPE / Gloves / Eye protection / Medical clothing Technical Specification**
Mod B Notified Body details, including address and NB number.