



CO-ORDINATION OF NOTIFIED BODIES
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Question related to PPE Regulation PPE Guidelines

EN/prEN:

Other:

EN 149:2001+A1:2009

Article:

Annex:

Clause:

Key words: colors, applied colors

Question:

- For filtering half masks supplied in a variety of colours, how should testing and certification be performed?
- Do the testing recommendations depend on how the color has been applied to the mask?

Information on possible color options:

The inner and outer layer or the entire filtering half mask can be coloured by mixing the color throughout the polymer material or the color can be applied onto the mask material by painting, printing, spraying, or coating. Different kinds of colors and their patterns can be applied e.g. for each batch. Also, the head bands can be coloured by mixing the color throughout the (polymer) material.

Inkjet technique is not covered by this RFU.

Solution for the question a)

Declarations of the manufacturer

If the manufacturer makes a written declaration that the material of the filtering half masks is consistent across the colors and that the colors do not affect performance, it is not necessary for the Notified Body to require the testing of each color. Below minimum recommendation for the tests should be followed.

If the manufacturer does not provide such a written declaration, complete testing of each color shall be performed.

The manufacturer shall declare for each colored version that the filtering half mask does not affect adverse effects on the user's health. The manufacturer shall declare that visibility and legibility are controlled for the markings of each color.

Minimum recommendation for the tests

For initial type-examination, the testing should include as wide range of the available colors supplied by the manufacturer as possible but perform testing using the standard sample quantities.

If the manufacturer wishes to add a color to a type-examined filtering half mask, which has no colored versions in initial testing, these tests are recommended for the first three color versions:

- EN 149:2001+A1:2009, 7.9.2 (Penetration of filter material), paraffin oil only, preconditioning of the samples: 3 AR, 3 SW and 3 MS+TC
- EN 149:2001+A1:2009, 7.16 (breathing resistance), preconditioning of the samples: 3 AR, 3 TC and 3 SW
- EN 149:2001+A1:2009, 7.11 (Flammability), preconditioning of the samples: 2 AR and 2 TC

If the manufacturer wishes to add even further colors with the same coloration technique, it is concluded that the coloration technique and the colors do not affect the performance of the filtering half mask and further testing is not needed.

EU type-examination

If any of the filter penetration, breathing resistance or flammability test results for a colored version is significantly different from the other test results, passing of all the tests of EN 149:2001+A1:2009 standard are required for the colored version. The magnitude of the significant difference shall be decided in EU type-examination.

The technical documentation shall describe each color or the coloring technique and color variability if the color and its pattern can be variable. The technical documentation shall include a written declaration to ensure that marking is visible and legible on each color of mask.

If the Notified Body deems it necessary, samples with markings can be requested in order to check the visibility and legibility of markings. For example, black marking on dark color is not acceptable.

If the EU type-examination certificate has a description or drawing for recognizing the filtering half mask, all colors shall be included, or in case of the variable colors and patterns produced, the coloring technique, and if possible, the limits of the colors shall be described.

Solution for the question b)

If the filtering half mask has any visible changes besides the color, e.g. surface structure of the colored layers, the mask shall be treated as different product.