	CO-ORDINATION OF NOTIFIED BODIES **PPE Regulation 2016/425** **RECOMMENDATION FOR USE**	PPE-R/02.075 Version 1

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☒ Other: COMMISSION RECOMMENDATION (EU) 2020/403 of 13 March 2020

Article: Annex: Clause:

Key words: certification of filtering half mask against SARS-CoV-2

Question:

According to Commission Recommendation (EU) 2020/403 of 13 March 2020 paragraph 3 and 4, what technical solutions could be used for EU type examination of Filtering half-mask against SARS-CoV-2?

Solution:

According to Commission Recommendation (EU) 2020/403 of 13 March 2020 paragraph 3 and 4 and actual WHO recommendations, FFP2 or equivalent filtering half-masks can be used for protection against SARS-CoV-2.

For EU type examination (annex V – module B – PPE regulation 2016/425):

If the manufacturer claims a general protection against particles, EN 149:2001+A1:2009 shall be used.

If the manufacturer claims protection against SARS-CoV-2 only :

- Requirements of EN 149:2001+A1:2009 class FFP2 modified as below can be used.
- Other international standards could be study by notified bodies. These standards should be used in respect with EHSR and other requirements of the PPE regulation 2016/425. In particular, markings and information for use shall be clear regarding the special use against SARS-CoV-2.

1. Description

§4 Description of EN 149:2001 + A1:2009 is applicable.

2. Designation

Filtering half masks meeting the requirements of this recommendation for use shall be designated in the following manner:

“filtering half mask to protect against COVID-19”

3. Requirements

3.1. General

§7.1 General of EN 149:2001 + A1:2009 is applicable.

3.2. Nominal values and tolerances

§7.2 Nominal values and tolerances of EN 149:2001 + A1:2009 is applicable.

3.3. Visual inspection

§7.3 Visual inspection of EN 149:2001 + A1:2009 is applicable.

3.4. Packaging

§7.4 Packaging of EN 149:2001 + A1:2009 is applicable.

3.5. Material

§7.5 Material of EN 149:2001 + A1:2009 is modified as below:

Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

Testing shall be done in accordance with 8.2

3.6. Cleaning and disinfecting

§7.6 Cleaning and disinfecting of EN 149:2001 + A1:2009 is modified as below:

If the particle filtering half mask is designed to be cleaned and disinfected, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.

Cleaning and disinfection method can be accepted only if they are scientifically proved in peer reviewed scientific publications effective against the SARS-CoV-2, or have been recommended by European Centre for Disease Prevention and Control, ECDC

Testing shall be done in accordance with 8.4.

With reference to 3.9, after cleaning and disinfecting the particle filtering half mask shall satisfy the penetration requirement.

Testing shall be done in accordance with 8.11.

3.7. Practical performance

§7.7 Finish of parts of EN 149:2001 + A1:2009 is applicable.

Requirement added :

During the practical performance test, the test subject should pay particular attention to the ability of the product to maintain a good faceseal. If the wearer observes that a good faceseal is not maintained, they shall be instructed to readjust the filtering half mask according to the user instructions. Should the test subject experience further difficulties with maintaining a good faceseal during the practical performance test, the filtering half mask shall be considered unsatisfactory.

3.8. Finish of parts

§7.8 Finish of parts of EN 149:2001 + A1:2009 is applicable.

3.9. Penetration of filter material

§7.9.2 Penetration of filter material of EN 149:2001 + A1:2009 is modified as below:

The penetration of the filter of the filtering half mask shall meet the requirements FFP2 of Table 1.

Table 1 — Penetration of filter material

Classification	[A1] Maximum penetration of test aerosol [A1]	
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

A total of 3 samples of filtering half masks shall be tested for each aerosol.

Testing in accordance with 8.11 using the Penetration test according to EN 13274-7, shall be performed on:

- for device without cleaning and disinfection process on:
  2 samples as received;
- for device with cleaning and disinfection process:
  2 samples after one cleaning and disinfecting cycle according to the manufacturer's instruction.

Testing in accordance with 8.11 using the Exposure test with a specified mass of test aerosol of 120 mg according to EN 13274-7, shall be performed:

- for device without cleaning and disinfection process on:
  1 sample as received;
- for device with cleaning and disinfection process on:
  1 sample after one cleaning and disinfecting cycle according to the manufacturer's instruction.

3.10. Compatibility with skin

§7.10 Compatibility with skin of EN 149:2001 + A1:2009 is modified as below:

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

Testing shall be done in accordance with 8.4.

3.11. Carbon dioxide content of the inhalation air

§7.12 Carbon dioxide content of the inhalation air of EN 149:2001 + A1:2009 is applicable.

3.12. Head harness

§7.13 Head harness of EN 149:2001 + A1:2009 is modified as below:

The head harness shall be designed so that the filtering half mask can be donned and removed easily.

The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the filtering half mask firmly in position..

Testing shall be done in accordance with 8.4.

3.13. Field of vision

§7.14 Field of vision of EN 149:2001 + A1:2009 is applicable.

3.14. Exhalation valve(s)

$7.15 Exhalation valve(s) of EN 149:2001 + A1:2009 is applicable.

3.15. Breathing resistance

$7.16 Breathing resistance of EN 149:2001 + A1:2009 is modified as below:

The breathing resistances apply to valved and valveless filtering half masks and shall meet the requirements FFP2 of Table 2.

Testing shall be done in accordance with 8.9.

Table 2 — Breathing resistance

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0,6	2,1	3,0
FFP2	0,7	2,4	3,0
FFP3	1,0	3,0	3,0

3.16. Demountable parts

$7.18 Demountable parts of EN 149:2001 + A1:2009 is applicable.

4. MARKINGS

4.1. Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

- The name, trademark or other means of identification of the manufacturer or supplier.
- Type-identifying marking.
- The intended use, which must be stated only as “Filtering half mask to protect against COVID-19”
- The number and version of This RFU. Eg ; PPE-R/02.075 version 1
- At least the month and year of end of shelf life. The end of shelf life may be informed by a pictogram.
- The sentence ‘see information supplied by the manufacturer’, at least in the official language(s) of the country of destination, or by using a pictogram.
- The manufacturer’s recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram.

4.2. Filtering half mask

Filtering half-mask against COVID-19 complying with this Recommendation for use shall be clearly and durably marked with the following:

- The name, trademark or other means of identification of the manufacturer or supplier.
- Type-identifying marking.
- The intended use, which must be stated only as “COVID-19”
- The number and version of This RFU. Eg ; PPE-R/02.075 version 1
- Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

5. Information to be supplied

- Information supplied by the manufacturer shall accompany every smallest commercial available package.
- Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.
- The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on
  - application/limitations;
  - the meaning of any colour coding;
  - checks prior to use;
  - donning, fitting. In particular, the user information shall includes a clear and comprehensive fit test and shall includes warnings that the fit is critical to the performance of the product
  - use;
  - maintenance (e.g. cleaning, disinfecting), if applicable;
  - storage;
  - the meaning of any symbols/pictograms used of the equipment.
- The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.
- Warning shall be given against problems likely to be encountered, for example:
  - fit of filtering half mask (check prior to use);
  - it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;
  - air quality (contaminants, oxygen deficiency);
  - use of equipment in explosive atmosphere.
- With the absence of a flammability test, a specific warning shall be included:
  - “Warning - this product is not flame resistant and must not be used in areas with open flames”
- The information shall provide recommendations as to when the filtering half mask shall be discarded.
- For devices without cleaning, disinfecting procedure, a warning shall be given that the filtering half mask shall not be used for more than one shift.
- The Information to be supplied by the manufacturer shall include the sentence:
  “This filtering half mask is manufactured for COVID-19 protection only. As requested by World Health Organization recommendations, for this specific use, the nominal protection factor given by this filtering half mask is the same than the FFP2 nominal protection factor defined in EN 149:2001+A1:2009. This filtering half mask is not a filtering half mask for general use and shall not be used for purposes other than protection against COVID-19.”

6. TESTING

Note : Paragraph numbers are kept from EN 149:2001 + A1:2009 for better understanding

8.1. General

§8.1 General of EN 149:2001 + A1:2009 is modified as below:

If no special measuring devices and methods are specified, commonly used devices and methods shall be used.

Before performing tests involving human subjects account should be taken of any national regulations concerning the medical history, examination or supervision of the test subjects.

8.2. Visual inspection

§8.2 Visual inspection of EN 149:2001 + A1:2009 is applicable.

8.3. Conditioning

8.3.4.Flow conditioning

§8.3.4 Flow conditioning of EN 149:2001 + A1:2009 is modified as below:

A total of 3 valved particle filtering half masks shall be tested:

- for device without cleaning and disinfection process on:

  3 samples as received;

- for device with cleaning and disinfection process on:

  3 samples after one cleaning and disinfecting cycle according to the manufacturer's instruction.

8.4. Practical performance

8.4.1.General

§8.4.1 General of EN 149:2001 + A1:2009 is modified as below:

1 particle filtering half mask shall be tested :

- for device without cleaning and disinfection process on:

  1 sample as received;

- for device with cleaning and disinfection process on:

  1 sample after one cleaning and disinfecting cycle according to the manufacturer's instruction.

All tests shall be carried out by one test subject at ambient temperature and the test temperature and humidity shall be recorded.

Prior to the test there shall be an examination to assure that the particle filtering half mask is in good working condition and that it can be used without hazard.

Examination shall be done in accordance with 8.2.

For the test, person shall be selected who are familiar with using such or similar equipment.

During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded:

a) head harness comfort;

b) security of fastenings;

c) field of vision;

d) maintenance of faceseal

e) any other comments reported by the wearer on request.

8.4.2.Walking test

§8.4.2 Walking test of EN 149:2001 + A1:2009 is applicable.

8.4.3.Work simulation test

§8.4.3 Work simulation test of EN 149:2001 + A1:2009 is applicable.

8.7. Carbon dioxide content of the inhalation air

§8.7 Carbon dioxide content of the inhalation air of EN 149:2001 + A1:2009 is applicable.

8.8. Strength of attachment of exhalation valve housing

§8.8 Strength of attachment of exhalation valve housing of EN 149:2001 + A1:2009 is modified as below:

A total of three particle filtering half masks shall be tested:

- for device without cleaning and disinfection process on:

  3 samples as received;

- for device with cleaning and disinfection process on:

  3 samples after one cleaning and disinfecting cycle according to the manufacturer's instruction.

8.9. Breathing Resistance

8.9.1.Test samples and fixture

8.9.1.1. Valveless particle filtering half mask

§8.9.1.1 Valveless particle filtering half mask of EN 149:2001 + A1:2009 is modified as below:

A total of three particle filtering half masks shall be tested:

- for device without cleaning and disinfection process on:
  3 samples as received;
- for device with cleaning and disinfection process on:
  3 samples after one cleaning and disinfecting cycle according to the manufacturer's instruction.

8.9.1.2. Valved particle filtering half mask

§8.9.1.2 Valved particle filtering half mask of EN 149:2001 + A1:2009 is modified as below:
A total of three particle filtering half masks shall be tested:
- for device without cleaning and disinfection process on:
  3 samples after the flow conditioning in accordance with 8.3.4;
- for device with cleaning and disinfection process on:
  3 samples after the flow conditioning in accordance with 8.3.4 and one cleaning and disinfecting cycle according to the manufacturer's instruction.

8.9.2.Exhalation resistance

§8.9.2 Exhalation resistance of EN 149:2001 + A1:2009 is applicable.

8.9.3.Inhalation resistance

§8.9.3 Inhalation resistance of EN 149:2001 + A1:2009 is applicable.

8.11. Penetration of filter material

§8.11 Penetration of filter material of EN 149:2001 + A1:2009 is applicable.

7. Correlation between the articles of PPE Regulation 2016/425 and this RfU

The following table shows the correlation between the essential health and safety requirements of Regulation 2016/425 of 9th march 2016 "Personal Protective Equipment" and the articles of this RfU.

PPE Regulation 2016/425 Annex II	**Clauses of this RfU**
1.1.1	3.7; 3.9
1.1.2.1	3.7; 3.9; 3.11
1.1.2.2	3.9
1.2.1	3.6; 3.11; 3.13; 3.15
1.2.1.1	3.5; 3.6; 3.7; 3.10
1.2.1.2	3.7; 3.8
1.2.1.3	3.7; 3.13
1.3.1	3.7
1.3.2	3.4; 3.5; 3.7
1.4	5
2.1	3.12
2.3	3.13
2.4	3.6; 4; 5
2.6	5
2.8	5
2.9	3.12 ; 3.16
2.12	4
3.10.1	3.6; 3.7; 3.8; 3.9; 3.11; 3.15; 4; 5