



CO-ORDINATION OF NOTIFIED BODIES
PPE Regulation 2016/425

PPE-R/03.031
Version 01

RECOMMENDATION FOR USE

Number of pages: 3	Approval stage :	Approved on :
Origin : VG 3	<input type="checkbox"/> Vertical Group <input checked="" type="checkbox"/> Horizontal Committee <input type="checkbox"/> EU PPE Working Group	19/06/2020
Question related to <input type="checkbox"/> PPE Regulation <input type="checkbox"/> PPE Guidelines <input type="checkbox"/> EN/prEN:	<input checked="" type="checkbox"/> Other: COMMISSION RECOMMENDATION (EU) 2020/403 of 13 March 2020	
Article:	Annex:	Clause:
Key words: Rapid testing of eye- and face protectors 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 rapid testing of eye- and face protectors against SARS-CoV-2?		
Solution: The procedure describes the testing, evaluation and certification of eye protection devices, face shields, goggles and safety spectacle. This document describes the minimum requirements and test procedures for eye and face protectors that are essential for healthcare workers, first responders and other personnel involved in the efforts to contain the virus and avoid the further COVID-19 spread. The specific requirements for eye protection devices are described in EN 166: 2001: Personal eye protection - Requirements. The test methods are described in EN 167: 2001 for optical test methods and in EN 168: 2001 for non-optical test methods. A simplified test procedure is applied for eye and face protectors (safety spectacles, goggles, face shields) that are tested and evaluated according to this test principle. The eye protection devices (goggles, face shields) that have been tested and assessed in this way may only be used by healthcare workers and emergency services personnel. Test report, technical documentation and information brochure are evaluated in full accordance with the PPER specifications; the product can then be certified according to PPER essential health and safety requirements .		

Requirements and tests

The following simplified test procedure applies to COVID-19 eye and face protectors:

Table 1 - Overview of the tests

Requirement in EN 166 : 2001	Clause in EN 166 : 2001	Number of samples	Clause in in EN 167 or EN 168	Remarks
Materials, general construction	6.1 6.2 7.1.3	6	167, 5	Innocuousness of the used materials, skin compatibility, potential for injury from sharp edges
Headbands	6.3	1		secure fit, only if headband is available
Field of vision and side protection	7.1.1	1	168, 17 168, 18	
Optical requirements - refractive powers - prism imbalance - transmittance / luminous transmittance - scattered light / light diffusion	7.1.2	6	167, 3 167, 4 167, 6	
Minimum robustness or Increased robustness at room temperature	7.1.4	4	168, 3 168, 4	Restriction: Deformation is allowed, but the product must not break.
Resistance to ignition	7.1.7	2	168, 7	
Protection against droplets and splashes of liquids	7.2.4	3 Brillen oder 1 Schild	168, 12 168, 10.2	optional, only applicable for goggles and visors
Information supplied by the manufacturer	10	1	-	Please note the restricted area of use and the restrictions, see 5
Marking	9	1	-	The label (including the manufacturer's code) is not required on the product itself, but shall be applied to each packaging unit.

NOTE:

6.3: please add adjustment and minimum width 10 mm

7.1.4: the robustness tests are not alternatives: goggles and face-shields require increased robustness. Please clarify what room temperature means. The standard requires -5/+55 °C conditioning.

7.1.5: from our understanding, ageing is not required. Is that correct?

9: The PPE must not be marked EN 166, but:

Option 1 RfU 03.031/V1- MANUF-1-3 (RFU-Identification of the manufacturer-Optical class-Marking for liquids)

or

Option 2 RfU 03.031/V1-COVID19- MANUF-1-3 (RFU-Identification of the manufacturer-Optical class-Marking for liquids)

Conformity assessment with restrictions

The manufacturer shall submit the technical documentation according to Annex 3 of the PPER

After checking and evaluating these documents, the notified body issues an EU type certificate (module B). It will be noted on this:

- Technical rule: RfU 03.031/Version 1
- The eye protection device (goggles and face shields) protects from droplets/splashes of liquids (depending on the type of protector)

Notes on intended use and user information

The user information to be included with the product or a packaging unit shall comply with clause 10 of EN 166. In addition, the following information shall be included, either in words or similar expressions:

- The eye protection device (spectacles, goggles and face shield) is only to be used by healthcare workers, first responders or emergency services and only for the duration of the current COVID-19 threat.
- The eye protection device (goggles and face shields) protects against droplets or splashes of liquids.
- If applicable: The eye protection device can be combined with surgical, filtering, half or full face masks (to be specified).
- If applicable: The eye protection device shall be disposed of after use!