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SUBJECT

Elaboration of a technical report for the determination of mechanical and functional properties of face shields.

BACKGROUND

MARTINSAN (BANDEX), S.A. contacts Aimplas in order to perform a list of tests on the face shields that it is manufacturing which are used as a mechanical barrier for those exposed to contamination from COVID-19.

These face shields can be regarded as complete eye protection without filtering action. Therefore, it is deemed convenient that they meet the requirements stated in standard UNE-EN 166 (April 2002), specially, those that apply to type 3 protectors "Droplets and splashes of liquids", as the application of the face shield to be tested is to be a mechanical barrier in the healthcare environment during the current state of pandemy. This product is of paramount importance at the moment as the sheet of the shield is exchangeable and can be cleaned using disinfectant liquids.

The eye protectors stated in the above mentioned standard must be approved by a control body. Nevertheless, due to the current situation, MARTINSAN (BANDEX), S.A. contacts AIMPLAS in order to test the most critical mechanical and functional properties to manufacture face shields that comply with the required face protection. Therefore, AIMPLAS is only a testing laboratory that issues a technical report that will not replace a CE Marking report issued by a Control Body.

AIMPLAS is the Plastics Technology Institute based in Valencia and it is registered in the Registry of Technology Institutes of the Ministry of Economy and Competitiveness. It belongs to the Spanish Federation of Technology Institutes, FEDIT, and to the Network of Technology Institutes of the Valencian Autonomy. The institute has more than 20 years of experience with plastic materials, as well as their transformation, and its technical activity is focused on clients from all the sectors where plastics are used: packaging, construction, automotive, recycling and environment, agriculture, electric and electronic, etc.

AIMPLAS offers a comprehensive and customized solution, coordinating and executing several activities on the areas of R&D projects, analysis and testing, technical advice, competitive and strategic intelligence and training.

AIMPLAS has a testing Laboratory accredited by ENAC, with accreditation number N° 56/LE156 according to standard UNE-EN ISO/IEC 17025 and, at the moment, is the laboratory in Spain with the broadest accreditation scope in plastics.

ENAC is the National Accreditation Body, the only national body able to guarantee technical capacity of the organizations that it accredits, following the policies and recommendations dictated by the European Union.

Accreditation is the formal recognition at international level that shows the capabilities and builds trust over the performance of different bodies, including analysis and testing laboratories.

TESTS

Determination of the properties of face shields according to standard UNE-EN 166 (April 2002) for the field of use 3: "Droplets and splashes of liquids" (Table 9).

- A.- Section 6.1.- General construction.
- B.- Section 6.2.- Materials.
- C.- Section 6.3.- Headbands.
- D.- Section 7.1.1.- Field of vision.
- E.- Section 7.1.2.2.2.- Transmittance.
- F.- Section 7.1.4.2.2.- Increased robustness.
- G.- Section 7.1.5.1.- Stability at an elevated temperature.
- H.- Section 7.1.7.- Resistance to ignition.
- I.- Section 7.2.4.- Droplets and splashes of liquids.

Note 1: corrosion test is not included (mentioned in Table 9) as it is considered as Non-Applicable because all the product is manufactured with plastic free of metallic parts.

SAMPLES

BANDEX PROTECTIVE SHIELD

- Code: 20-1240-1

- Description: Face shields





TEST METHOD

A.- General construction

- Method:
 - a) Visual inspection
 - b) Measurement of dimensions: according to the manufacturer's drawing attached in Annex II
 - c) Measurement of the thickness of the shield sheet
- Tested sample: whole face shield (diadem included)
- Used testing equipment: outside micrometer and rigid ruler
- N° of tested samples: 1
- Conditioning: 1 hour at $(23 \pm 2) ^\circ\text{C}$ and $(50 \pm 10) \% \text{RH}$
- Environmental conditions: $(23 \pm 2) ^\circ\text{C}$ and $(50 \pm 10) \% \text{RH}$

B.- Materials

- According to the documents provided by the client and attached to Annex III of this report
- Tested sample: whole face shield (diadem included)
- N° of tested samples: 1
- Conditioning: 1 hour at $(23 \pm 2) ^\circ\text{C}$ and $(50 \pm 10) \% \text{RH}$
- Environmental conditions: $(23 \pm 2) ^\circ\text{C}$ and $(50 \pm 10) \% \text{RH}$

C.- Headbands

- Method:
 - a) Visual inspection
 - b) Measurement of the width of the band
- Tested sample: whole face shield (diadem included)
- Used testing equipment: digital caliper
- N° of tested samples: 5
- Conditioning: 1 hour at $(23 \pm 2) ^\circ\text{C}$ and $(50 \pm 10) \% \text{RH}$
- Environmental conditions: $(23 \pm 2) ^\circ\text{C}$ and $(50 \pm 10) \% \text{RH}$

D.- Field of vision

- Method: according to section 18 of standard UNE-EN 168 (April 2002)
- Procedure: the face shield is built on a medium-sized head and a beam of laser light is projected according to figure 12 of the standard
- Tested sample: whole face shield (diadem included)
- N° of tested samples: 1
- Conditioning: 1 hour at $(23 \pm 2) ^\circ\text{C}$ and $(50 \pm 10) \% \text{RH}$
- Environmental conditions: $(23 \pm 2) ^\circ\text{C}$ and $(50 \pm 10) \% \text{RH}$

E.- Transmittance

- Method: according to section 6 of standard UNE-EN 167 (April 2002) for eye protection without filtering action
- Tested sample: whole face shield (diadem included)
- Used testing equipment: transmittance measuring device
- Illuminant: CIE light A (2856 K)
- N° of tested samples: 5
- Conditioning: 1 hour at $(23 \pm 2) ^\circ\text{C}$ and $(50 \pm 10) \% \text{RH}$
- Environmental conditions: $(23 \pm 2) ^\circ\text{C}$ and $(50 \pm 10) \% \text{RH}$

**F.- Increased robustness**

- Method: according to section 3.2 of standard UNE-EN 168 (April 2002)
- Procedure: the screens are conditioned at two temperatures indicated in the test standard and an impact test is performed over the shield placed on a medium-sized head using a steel ball of 22mm of nominal diameter and a mass of 55 grams at a speed of 5 m/s.
- Tested sample: whole face shield (diadem included)
- Impact areas:
 1. Frontal, left eye
 2. Frontal, right eye
 3. Lateral, left eye
 4. Lateral, right eye
- Used conditioning equipment: climatic chamber
- N° of tested samples: 8 (1 for each impact area and 4 for each conditioning)
- Conditioning:
 - a) 1 hour at $(55 \pm 2) ^\circ\text{C}$
 - b) 1 hour at $(-5 \pm 2) ^\circ\text{C}$
- Environmental conditions: $(23 \pm 2) ^\circ\text{C}$ and $(50 \pm 10) \% \text{ RH}$

G.- Stability at an elevated temperature

- Method: visual inspection after conditioning according to section 5 of the standard UNE-EN 168 (April 2002)
- Tested sample: whole face shield (diadem included)
- Used conditioning equipment: climatic chamber
- N° of tested samples: 1
- Test temperature: $(55 \pm 5) ^\circ\text{C}$
- Duration of test: 60 minutes
- Estabilización posterior: 60 minutes at $(23 \pm 2) ^\circ\text{C}$

H.- Resistance to ignition

- Method: according to section 7 of the standard UNE-EN 168 (April 2002)
- Procedure: a hot steel rod is brought into contact with the outer parts of the face shield during a specified time
- Tested sample: whole face shield (diadem included)
- N° of tested samples: 1
- Rod: made of steel and 6 mm diameter
- Conditioning temperature of the rod: $(650 \pm 20) ^\circ\text{C}$
- Used heating device: muffle
- Rod heating time: 3 hours
- Test duration: contact time, 5 seconds
- Environmental conditions: $(23 \pm 2) ^\circ\text{C}$ and $(50 \pm 10) \% \text{ RH}$

I.- Droplets and splashes of liquids

- Method: according to section 18 and 12 of the standard UNE-EN 168 (April 2002)
- Procedure: for face shields it is enough to perform the field of vision test described on section D of this report



RESULTADOS

A.- General construction

Test date: 12/05/2020

- a) Visual inspection: face shields do not show protrusions, sharp edges or other defects that may cause discomfort or injury during use. Nevertheless, special care is recommended with the sheet edges that make up the transparent shield. Moreover, when looking through backlighting, no structural damages are observed, such as wave nor strips that may impeded vision.
- b) Dimensions measurement:

Table 1

Dimension	Measurement (mm)
A	210
B	270,5
C	90,5
D	79,0
E	89,5
F	6,0
G	190
H	144
I	33,33
J	19,92

- c) Measurement of the thickness of the shield sheet

Tabla 2

Specimen	Thickness (μm)
1	302
2	298
3	299
4	302
5	300
6	301
7	296
8	299
9	300
10	302
Average	300
Standard deviation	2

**B.- Materials**

Test date: 12/05/2020

Technical data sheets of the materials employed by the manufacturer of the product are attached in Annex III and have been supplied by the client. No reference regarding skin irritation is found on the technical data sheets due to the use of those products, although the materials are not considered to cause potential irritation and/or allergies.

C.- Headbands

Test date: 12/05/2020

- a) Visual inspection: all headbands used are found to be adjustable
- b) Measurement of the width of the band:

Table 3

Measurement point	Front area	Side area
1	14	10
2	14	10
3	14	10
4	14	10
5	14	10
Average	14	10
Standard deviation	<1	<1

D.- Field of vision

Test date: 12/05/2020

The laser beam is not intercepted by the shield. The field of vision of the user is not blocked in any of the projections. Therefore, the shields have a complete frontal and lateral field of vision.

E.- Transmittance

Test date: 12/05/2020

Table 4

Specimen	Luminous transmittance (%)
1	90,4
2	90,4
3	90,4
4	90,4
5	90,4
Average	90,4
Standard deviation	0

Note 2: The shield does not have any filtering action, that is why it is recommended to be used together with an eye protection equipment in case the shield has to be used for optical radiation.

F.- Increased robustness

Test date: 12/05/2020

Table 5

Impact area	Result	
	After 1 hour at (55 ± 2) °C	After 1 hour at (-5±2)°C
Frontal, left eye	Light marks of the tracing paper are observed on the paper, but no remaining deformation nor cracks are observed on the face shield after impact	No remaining deformation nor crack are observed on the face shield after impact
Frontal, right eye	Marks of the tracing paper are observed on the paper, but no remaining deformation nor cracks are observed on the face shield after impact	Light marks of the tracing paper are observed on the paper, but no remaining deformation nor cracks are observed on the face shield after impact
Lateral, left eye	Marks of the tracing paper are observed on the paper, but no remaining deformation nor cracks are observed on the face shield after impact	Marks of the tracing paper are observed on the paper, but no remaining deformation nor cracks are observed on the face shield after impact
Lateral, right eye	Marks of the tracing paper are observed on the paper, but no remaining deformation nor cracks are observed on the face shield after impact	Marks of the tracing paper are observed on the paper, but no remaining deformation nor cracks are observed on the face shield after impact

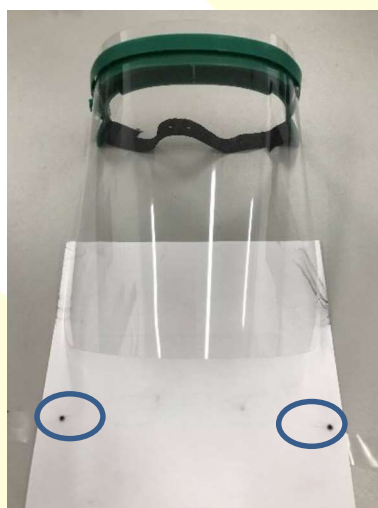


Figure 1. Example of the light impact marks over the white paper through tracing paper in the cases in which a mark is produced, although no remaining deformation is observed.

G.- Stability at an elevated temperature

Test date: 12/05/2020

No deformations, defects or loss of functionality are observed after test.



Figure 2. Face shields, left before and right after the stability at an elevated temperature test.

H.- Resistance to ignition

Test date: 12/05/2020

In no area exposed to the outside, headband nor screen, the material is observed to ignite nor continue to glow after the steel rod is removed from the testing area. Nevertheless, a contraction of the material on the contact area with the rod is observed. Holes and own coloration of the plastic exposed to high temperatures are observed.



Figure 3. Marks after hot steel rod application.

I. Droplets and splashes of liquids

Test date: 12/05/2020

According to section D of this report, the laser beam is not intercepted by the shield and it does not block the field of vision of the user in any of the projections made. Therefore, the shields have a complete frontal and lateral field of vision, thus protecting the shield from potential splashes of liquids.

Note 3: A summary of the obtained results are shown on Annex I of this report.



ANNEX I

Hereafter a summary table with the obtained results in this report is shown, together with the requirements established for complete eye protection equipments, the face shields under study.

BANDEX PROTECTIVE SHIELD						
Test	Test standard	Requirements according to product standard UNE-EN 166 Field of use 3 Droplets and splashes of liquids		Result		Conclusion
General construction	UNE-EN 166	Eye protectors must be free of protrusions, sharp edges or other defect that may cause discomfort or injury during use.		Eye protectors are free of protrusions, sharp edges or other defect that may cause discomfort or injury during use.		OK ⁽¹⁾
Materials	UNE-EN 166	No part of the eye protection that is in direct contact with the user should be made of materials known to cause irritation of the skin		The technical data sheets of the employed materials do not show any reference of skin irritation		OK
Viewer	Recommendation	Material	Transparent: cellulose acetate, PVC, polycarbonate, PET, etc.	See Technical Data Sheets Annex III		OK
		Finish	Backlighting observation of the material that no structural defects, such as ripples, horizontal strips, etc. are observed	Backlighting observation does not show structural defects		
		Measurement	See drawing in Annex II ⁽²⁾	See Table 1		
		Thickness (µm)	≥ 230 ⁽³⁾	300		
	UNE-EN 167	Transmittance (%)	≥ 74,4	90,4		OK ⁽⁴⁾
Headbands (mm)	UNE-EN 166	Width ≥ 10		Frontal area	14	OK
				Lateral area	10	
		Adjustable		Adjustable		
Field of vision	UNE-EN 168	Eye protectors must have a field of vision that does not interrupt the eyes nor the lateral vision.		Eye protectors have a complete field of vision, both frontal and lateral		OK
Increased robustness	UNE-EN 168	No fractures nor deformations should appear on the eye protection		No remaining deformation nor fracture are observed on the eye protection after impact		OK ⁽⁵⁾
Stability at an elevated temperature	UNE-EN 168	No deformations nor defects should appear on the eye protection		No deformations nor defects appear on the eye protection		OK
Resistance to ignition	UNE-EN 168	No part of the eye protection iginites nor continues incandescent after the rod has been removed		No part of the eye protection iginites nor continues incandescent after the rod has been removed		OK ⁽⁶⁾
Droplets and splashes of liquids	UNE-EN 168	Face shields must have a complete field of vision, both frontal and lateral		Face shields have a complete field of vision, both frontal and lateral		OK

⁽¹⁾ It is recommended to be careful with the edges of the sheet that makes up the transparent shield.

⁽²⁾ Requirement not included in the standard UNE-EN 166, but established on the drawing of the manufacturer, attached on Annex II.

⁽³⁾ Requirement not included on the standard UNE-EN 166, but established as a minimum to assure functionality.

⁽⁴⁾ It is recommended to use an specific eye protection equipment when using the face shield in front of specific optical radiations

⁽⁵⁾ Although slight marks appear during the test, no remaining deformation is observed.

⁽⁶⁾ Compliance with this requirement is not considered critical as it is not included in the required functionalities of the healthcare field.



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