

Integrated mask performance assay report

Applicant: ATQ QUIMYSER, S.L.





Summary

1. Object and scope of the report	3
2. Sample description	4
2.1. Description and identification of the tested sample	4
2.2. Inspection before the assay	5
3. Assay methodology	5
4. Results	7

1. Object and scope of the report

This report includes the results of examinations, tests and observations made on samples of a community face coverings (reusable hygienic masks in Spain) manufactured with 4 layers of non-woven polypropylene fabric sent by the company ATQ QUIMYSER, S.L. in the context of the COVID-19 health crisis, and marketed under the seal of Sanisport..



The masks covered by this report are not to be considered as medical devices (MP) in the sense of Directive 93/42 EC or Regulation EU/2017/745, nor as personal protective equipment (PPE) in the sense of Regulation EU/2016/425.

The masks under the subject of this report have been studied in order to verify their compliance with the standard UNE-CWA 17553:2020 "Community face coverings. Guide to minimum requirements, methods of testing and use".

The standards applied and the parameters studied in the tests included in this report are detailed in the following table.

Table 1. Performed assays

Assay	Standards / sections	Assay section
Breathability (Differential pressure), (Pa/cm²)	UNE 0065 specification	6.5
	UNE-CWA 17553	Annex
	UNE-EN 14683:	C
	2019 + AC: 2019	
Filtering material penetration	UNE-CWA 17553	6.4
	UNE-EN 13274-7:2008	5.3 (Table 2)
	(6.1, 6.2, 6.3, 6.4, 6.5)	6.1
Visual inspection	UNE 0065 specification	6.2
	UNE-CWA 17553	8.2

2. Sample description

2.1. Description and identification of the tested sample



The evaluated samples correspond to a 4-layer hygienic mask model manufactured by the company ATQ QUIMYSER, S.L based on the standard UNE-CWA 17553:2020 “Community face coverings”, one of which has not been made any washing process and the other 2 have received different washing processes by the company, which are detailed in table 1.

The hygienic mask is a product that covers the mouth, nose and chin, is made of a suitable filtering material, is manufactured with a material that allows breathing, uses materials that in contact with the user’s skin do not present known risks of irritation or adverse health effects, and ensures a proper fit with the face.

The hygienic mask can be formed by one or several layers (of one material or a combination of materials), as long as it meets the acceptance criteria indicated by the standard UNE-CWA 17553:2020 in terms of breathability and filtration efficiency. Changes in design, materials or manufacturing methods will be the responsibility of the manufacturer and must comply in all cases with the criteria of filtration and breathability.

The tested mask model is shown in the next figure.



Figure 1. Used mask model pictures

The following table shows images of the analysed mask models

Table 2. Samples description

Samples	Description	Picture
ATQ QUIMYSER_EPR_1 (Original)	4-layer basic hygienic die-cut non-woven half-mask unwashed . Classification: Reusable hygienic mask	
ATQ QUIMYSER_EPR_2 (25 washes)	4-layer basic hygienic die-cut non-woven half-mask washed* Classification: Reusable hygienic mask	

***Note:**

Note on the washing process: application of SANISPORT DESINFECTANT LOTION product for 5 minutes, which is included in the list of approved virucidal products by the Ministry of Health followed by rinsing with water + non sunlight mediated drying process

2.2 Inspection before the assay

Table 3. Status of samples on receipt at the laboratory



Samples	Description	Status
ATQ QUIMYSER_EPR_1 (Original)	4-layer basic hygienic die-cut non-woven half-mask unwashed . Classification: Reusable hygienic mask	Good conservation state
ATQ QUIMYSER_EPR_2	4-layer basic hygienic die-cut non-woven half-mask washed (25 washes)* Classification: Reusable hygienic mask	Good conservation state

***Note:**

Note on the washing process → application of SANISPORT DESINFECTANT LOTION product for 5 minutes, which is included in the list of approved virucidal products by the Ministry of Health followed by rinsing with water + non sunlight mediated drying process

3. Assay methodology / set up

The applied assay methodologies are based on the testing criteria and information requirements set out in the standards UNE – CWA 17553 , EN 14683:2019+AC:2019, and the UNE 0065 specification.

The standard UNE – CWA 17553 establishes the acceptance criteria regarding the breathability (differential pressure) of the materials and filtration efficiency (%). The material's breathability tests have been carried out by the AITEX notified body. For its part, the ITENE research center has carried out the filtration efficiency study of the non-woven fabric used in the mask.

The type of test and associated requirements evaluated are detailed in the following table:

Table 4. Assay parameters and used equipment

Assay	Standard	Assay date	Parameter
Breathability (Pa/cm2)	UNE-CWA 17553 UNE-EN 14683: 2019 + AC: 2019	01/08/2020	Pressure difference that is needed to pass air through a surface area measured at a constant air flow, in order to measure the air exchange pressure of the material.
Filtering material penetration	UNE-CWA 17553 UNE-EN 13274- 7:2008 (6.1, 6.2, 6.3, 6.4, 6.5)	01/08/2020	Measure of the percentage of particles around 3 (± 0,5) µm that can pass through the filter media as endpoint to estimate the filtration efficiency. Measurement devices: optical particles sizer following the specifications laid down on UNE-CWA 17553

Table 5. Test parameters and compliance requirements



Assay	Standard	Evaluated requirement						
Breathability (Pa/cm ²)	UNE-CWA 17553	The pressure difference must meet the requirements set out in the table below:						
	UNE-EN 14683: 2019 + AC: 2019							
		<table border="1"> <thead> <tr> <th colspan="2">Acceptance criteria</th> </tr> </thead> <tbody> <tr> <td>Breathability</td> <td>< 60 Pa/cm²</td> </tr> </tbody> </table>	Acceptance criteria		Breathability	< 60 Pa/cm ²		
Acceptance criteria								
Breathability	< 60 Pa/cm ²							
Filtering material penetration	UNE-CWA 17553	The filter penetration of the half-mask filter must meet the requirements set out in the table below:						
	UNE-EN 13274-7:2008 (6.1, 6.2, 6.3, 6.4, 6.5)							
		<table border="1"> <thead> <tr> <th colspan="2">Criteria</th> </tr> </thead> <tbody> <tr> <td>Acceptance</td> <td>level 90%: greater than or equal to 90%</td> </tr> <tr> <td></td> <td>level 70%: greater than or equal to 70%</td> </tr> </tbody> </table> <p>* According to SOP filtration</p>	Criteria		Acceptance	level 90%: greater than or equal to 90%		level 70%: greater than or equal to 70%
Criteria								
Acceptance	level 90%: greater than or equal to 90%							
	level 70%: greater than or equal to 70%							
Visual inspection	-	Visual inspection before the assay						

4. Results

Below are the results obtained in the performed examinations, tests and determinations.

Sample ATQ QUIMYSER_EPR_1: 4-layer basic Reusable hygienic masks unwashed



Assay	Specification	Result
Visual inspection		Successful
Breathability	Pressure difference needed to pass air through	$16 \pm 0 \text{ Pa/cm}^2 (< 60 \text{ Pa})$
Particle filtration	Maximum filter penetration / retention (%) Classification: Reusable hygienic masks	Penetration value / retention: 4,40 % / 95,60%
	Filter material level	90 - pass

Sample ATQ QUIMYSER_EPR_2: 4-layer basic Reusable hygienic masks washed (25 washes)

Assay	Specification	Result	Conclusion
Visual inspection		Successful	Meet requirements
Breathability	Pressure difference needed to pass air through	$16 \pm 0 \text{ Pa/cm}^2 (< 60 \text{ Pa})$	
SOP filtration particle	Maximum filter penetration / retention (%) Classification: Reusable hygienic masks	Penetration value / retention: 4,80 % / 95,20 %	
	Filter material level	90	Pass

Clauses:

The determined results refer exclusively to the materials or samples indicated in the report, as well as to the used analysis methods.



Developed and approved
Signature

A handwritten signature in blue ink, appearing to read "Carlos Fito López", written over a light blue grid background.

Carlos Fito López
Particle Safety Unit Responsible

ITENE RESEARCH
CENTER

Parque Tecnológico
C/ Albert Einstein, 1 / 46980 Paterna / Valencia, Spain
(+34) 96 182 00 00 / info@itene.com / www.itene.com