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# Test 1: Bacterial Filtration efficiency BFE - Summary of the obtained results

### **Test conditions**

	Unit	Target	Result	
(P) Positive tests - average of totals (CFU)	[CFU]	1700 ≤ x ≤ 3000	2150,5	
Positive test - Mean Particle Size (MPS)	[µm]	2.7 ≤ x ≤ 3.3	2,8	
Negative test - Average CFU counted	[CFU]	<1	< 1	

### Test results

Mask	Result of the Bacterial Filtration Efficiency (BFE) obtained	Best classification (Type)	Raw data cf. Annex 1 Page :
	[%]		
Mask 1	99,9	Type II/Type IIR	3
Mask 2	99,8	Type II/Type IIR	4
Mask 3	99,7	Type II/Type IIR	5
Mask 4	100,0	Type II/Type IIR	6
Mask 5	99,9	Type II/Type IIR	7

## Average BFE efficiency for this series of masks in%

99,9

Best classification result (type) obtained for this series of masks

Category (ies) assigned according to the performance requirements of EN 14683 + AC: 2019:

Test	Type I*	Type II	Type IIR	
Bacterial Filtration Efficiency (BFE) [%]	≥ 95	≥ 98	≥ 98	
Microbial cleanliness [cfu/g]	≤ 30	≤ 30	≤ 30	

Average Bacterial Filtration Efficiency	Target of the best obtained category	Category of the best obtained target	AQL Criteria**	Percentage of acceptable quality samples obtained: ***	Compliance status WITH standard EN 14683 + AC: 2019 AQL ** for BFE	Compliance status WITHOUT the normative criteria EN 14683 + AC: 2019 AQL **
99,9 [%]	≥ 98	Type II/Type IIR	96 [%]	100 [%]	Compliant	Compliant

The results of the tests carried out also satisfy the requirements for 'community' masks §8.4 of standard NBN S65-001:2020 (BFE greater than à 70%)

Is the category (type) of mask claimed by the client or displayed clearly on the packaging of the masks?		Yes
What is the category (type) of mask assigned by the client?	Type I	
	Type II	
	Type IIR	X
Does the best result category obtained correspond to and satisfy this classification?		Yes

<sup>\*</sup> As a reminder, masks for medical use of type I should only be used for patients and other people, to reduce the risk of spread of infection, especially in the context of an epidemic or pandemic. Type I masks are not intended for use by healthcare professionals in operating rooms or other medical facilities with similar requirements. (§5.2.7 EN14683 + AC: 2019)

HeX recalls the importance of verifying the information on the packaging on page 5 for the interpretation of the results

<sup>\*\* &</sup>quot;At least five samples must be tested, but their number can be increased, if necessary, to achieve an acceptable level of quality of 4%" (EN 14683 + AC: 2019). Or, at least 96% of the individual values compliant to the expected target.

<sup>\*\*\*</sup> Samples that do not meet the expected acceptable quality level (AQL) are identified in Annex 1 with the following mention: "AQL \*\*\*\*"
Status and decision rule: Measurement uncertainties are not taken into account in the declaration of conformity for the various tests.



# Differential pressure / Breathability [Pa/cm²]

Test reference:	Mask:	Average differential pressure [Pa/cm²] :	Raw data cf. Annex 1 Page:
Réf0 M1	М1	46,0	1
Réf0 M2	M2	40,6	2
Réf0 M3	M3	36,3	3
Réf0 M4	M4	38,4	4
Réf0 M5	M5	43,0	5

### Average of differential pressure masks [Pa/cm<sup>2</sup>]

40.8

Global compliance status according to EN 14683 + AC: 2019\*\*\*\*

Category (ies) assigned according to the performance requirements of EN 14683 + AC: 2019:

Test	Type I*	Type II	Type IIR	
Bacterial filtration efficiency (BFE) [%]	≥ 95	≥ 98	≥ 98	
Differential pressure [Pa/cm²]	< 40	< 40	< 60	
Spray resistance pressure [kPa]	Not required	Not required	≥ 16.0	
Microbial cleanliness [cfu/g]	≤ 30	≤ 30	≤ 30	

Average of differential pressure masks [Pa/cm²]	Type of mask claimed :	AQL criterion **	Percentage of acceptable quality sample obtained: ***	Compliance status WITH the normative criterion EN 14683 + AC: 2019 AQL **	Compliance status WITHOUT the normative criterion EN 14683 + AC: 2019 AQL ** Reminder of the result of the estimation of the uncertainties on the test: ± 1.33 Pa/cm <sup>1</sup>
40,8 [Pa/cm²]	Type IIR	96 [%]	100 [%]	Compliant	Compliant

The results of the tests carried out satisfy the requirement of "Community" masks in §8.5 of standard NBN S65-001: 2020 (\(Diff\) less than 70 [Pa / cm²])

Differential pressure results cannot be extrapolated to another situation without considering all the data related to specific conditions. (e.g. brand/model, see batch number)

Status and decision rule: measurement uncertainties are not taken into account in the declaration of compliance of the different tests.

<sup>\*</sup> As a reminder, masks for medical use of type I should only be used for patients and other people, to reduce the risk of spread of infection, especially in the context of an epidemic or pandemic. Type I masks are not intended for use by healthcare professionals in operating theaters or other medical facilities with similar requirements. (§5.2.7 EN14683 + AC: 2019)

<sup>\*\* &</sup>quot;At least five samples must be tested, but their number can be increased, if necessary, to allow an acceptable quality level of 4% to be obtained" (EN 14683 + AC: 2019 § C.3). Or, at least 96% of the individual values conform to the expected target.

<sup>\*\*\*</sup> Samples that do not meet the expected acceptable quality (AQL) are identified in Annex 1 with the following mention: "AQL \*\*\*"

<sup>\*\*\*\*</sup> If the status is not in conformity, HeX draws your attention to the particularity of paragraph 5.2.3 of EN 14683 + AC: 2019. Indeed, "if the use of a respiratory protective device as a mask is required in an operating theater and/or other medical facility, it may not meet the performance requirements for differential pressure defined in this European Standard. the device meets the requirement specified in the relevant standard (s) on personal protective equipment (PPE)". In this case (if the mask presented by the client is a surgical mask), please get in touch with HeX to discuss the subject.