Combined test report:
Test 1: Bacterial Filtration Efficiency (BFE) on masks for medical use
Test 2: Microbial cleanliness (bioburden) test on masks for medical use

Client:	UltraFilter GmbH Otto-Hanh StraBe 1 40721 HILDEN
Group:	UltraFilter GmbH
Name of client referent	Herr Kronsbrein
Site client:	UltraFilter GmbH Otto-Hanh StraBe 1 40721 HILDEN
Location of measurements:	HeX Lab Porte des Batisseurs , 145 B-7730 Estaimpuis

FI identification number:	201100
Report identification number:	ULTRA01-2-04-200629-1_LAB BFE_BB
Version of report:	1
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Brand:	UltraMask
Reference:	EASM 198R
Test required under:	BFE test: EN14683+AC :2019_Annex B Microbial cleanliness test: EN14683 + AC: 2019_Annex D
Operating procedure:	BFE test: 7.2 - LABExe-Mo12 Microbial cleanliness test: 7.2 - LABExe-Mo13
Operator(s):	Elisa Salgado
Report edited by:	Elisa Salgado

Reviewed and Approved by:

Approved by Aurélie Tirloy Technical Manager HeX LAB
HeX GROUP
Your expert in contamination control
Signature numérique de Quality Unit
Date : 2020.07.08 16:05:18 +02'00'

Foreword & context (1/2)

EN 14683+AC:2019

The EN 14683+AC:2019 standard specifies the requirements and test methods related to masks for medical use.

Mask for medical use: medical device covering the mouth and nose, which constitutes a barrier making it possible to minimize the direct transmission of infectious agents between the medical team and the patient

Differential pressure: air permeability of the mask, measured by determining the pressure difference across the mask under specific conditions of air flow, temperature and humidity

Bacterial Filtration Efficiency (BFE): effectiveness of the materials of the mask for medical use as a barrier against bacterial penetration

Colonial Forming Unit (CFU): unit in which the number of cultivable microorganisms is expressed

Aerosol: gaseous suspension of solid and / or liquid particles

Resistance to projections: capacity of a mask for medical use to resist the penetration of synthetic blood projected at a given pressure. (This test is required only for type IIR)

Recovery efficiency: Measure of the capacity of a given technique to extract, sample and / or cultivate microorganisms from a product

IPS Individual Product Subdivision: A defined part of a health product under test. A IPS = 1.0 corresponds to the entire product.

Bioburden correction factor: numerical value applied to a number of viable microorganisms to compensate for the incomplete extraction of microorganisms from a product and / or the failure to culture microorganisms.

Classification

Masks for medical use are classified into two types (I and II) according to the bacterial filtration efficiency (BFE) and the differential pressure, after which an additional subdivision is made for type II according to whether or not it is resistant to projections. The letter "R" indicates resistance to projections.
The compliance status is therefore established by HeX based on the results obtained and the performance requirements of the type of mask for medical use announced by the client. (see table below).

Test conditions

Several conditions must be met for the test result to lead to compliance status. HeX makes every effort to meet these conditions:
1. average particle size (3,0 ± 0,3) µm
2. average positive test between 1700 and 3000 CFU
3. negative test less than 1 CFU

If, however, one or more of these conditions cannot be met, HeX reserves the right to give the raw result for information only, without compliance status. HeX would not be held responsible for this.

Table of performance requirements for medical masks (§5.2.7 EN14683+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

* Type I medical masks should only be used for patients and others to reduce the risk of spreading infection, especially during 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.

Foreword & Context (continued 2/2)

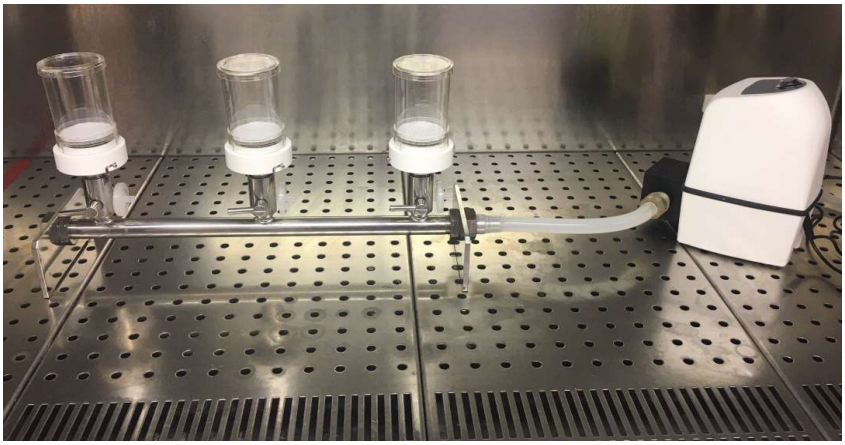
Responsibilities and customer

The responsibility of the client is required on the following points, throughout the study:
- Deliver masks of the same brand, same model
- Supply of masks in quantity and according to associated HeX Quote
- The masks will be sent at his expense and under his responsibility
- Strict compliance with traceability and nomenclature conditions as well as filling in the traceability and link sheet associated with the package.

Test bench (photograph)

Test 1: Bacterial Filtration Efficiency (BFE)

Test 2: Microbial cleanliness



Document information

Version:	1,07
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Version reviewed and validated by:	Aurélie Tirloy – Technical Manager
Validité du rapport :	Only the latest electronic version available on the server is deemed authentic. The test report may not be reproduced, if not in its entirety, without the written permission of the laboratory. The results of the test report only refer to the tested objects.
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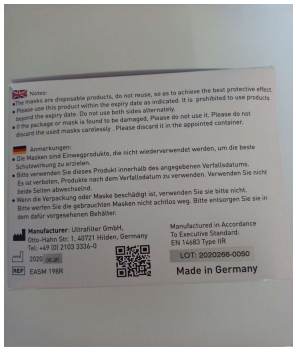
Revision:	The signed final report cancels all communicated interim results and documents. Each revision cancels and replaces the previous one. Any outdated draft must be destroyed as well as any copy that may have been made.
Decision rule:	Measurement uncertainties are not taken into account in the declaration of compliance of the different tests.
Dessimation & authorities:	HeX informs that on simple request of the authorities, HeX may be required to disclose confidential information, such as test reports.

Packaging masks

Inscription or Mention on packaging	Present (box checked)	Conclusion
"medical", "chirurgical" or "surgical"	X	If present, then this information contributes to claiming a mask for medical use
EN 14683	X	If present, then this information contributes to claiming a mask for medical use
GB 19083 (medical use)		If present, then this information contributes to claiming a mask for medical use
Classification or category indicated: type I, II or IIR	X	If present, then this information contributes to claiming a mask for medical use
BFE (Bacterial Filtration Efficiency)		If present, then this information does not contribute to claiming a mask for medical use
% efficiency		If present, then this information does not contribute to claiming a mask for medical use
GB 2626 (Non medical use)		If present, then this information contributes to claim the NON-MEDICAL USE of these masks
Packaging, bow without any inscription		If present, then this information contributes to claim the NON-MEDICAL USE of these masks
"non medical" - "for civil" - "comfort" - ...		If present, then this information contributes to claim the NON-MEDICAL USE of these masks
Other(s)		If present, then this information contributes to claim the NON-MEDICAL USE of these masks

HeX recalls that the test results in this report are obtained in accordance with the requirements of a normative test method. These test results alone cannot claim the medical use of these masks. Indeed, the conclusions in the table above, linked to the information on the packaging of the masks, must also be taken into account when determining the use of the masks considered.



Test 1: Test conditions BFE -test - Normative requirements

Bacterial inoculum		Test parameters	
Test microorganism	*Staphylococcus aureus*	Sample measurement	minimum 100 mm × 100 mm
Culture medium	Trypticase Soy Broth	Test area	minimum 49 cm²
Incubation temperature	(37 ± 2) °C		
Incubation time	(24 +/-) 2 h	Flow active air sampler	28,3 l/min
dilution medium	Peptone water	Flow direction	from inside to outside of the mask
Bacterial inoculum	1,7 × 10^3 CFU to 3,0 × 10^3 CFU per test	Sample conditioning	min 4h30 at 21 ± 5 [°C] and 85 ± 5 [%RH]

Test conditions

Duration of the test	1 min diffusion of bacterial inoculum + 1 min only air flow
Culture media	Trypticase soy agar
Incubation temperature	(37 ± 2) °C
Incubation time	20 h to 52 h
Bacterial inoculum	1,7 × 10^3 CFU to 3,0 × 10^3 CFU per test
Mean Particle Size (MPS)	(3,0 +/- 0,3) µm

Test 2: Conditions for the microbial cleanliness test - Normative requirements

Test conditions

IPS retained:

Recovery Liquid: Tryptone Soya Broth With 0.3% Lecithin and 2.0% Tween
Volume of recovery liquid: 100 ml
Temps d'agitation : 5 minutes
Agitation time: 5 minutes
Filtered volume: 100 ml
Filtration membranes: sterile membrane with a porosity of 0.45 µm
Plate for the enumeration of Total Mesophilic Aerobic Flora: Trypticase Soy Agar
Plate for enumeration of yeasts and total molds: Sabouraud Dextrose Agar + Chloramphenicol

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	2177,5
Positive test - Mean Particle Size (MPS)	[µm]	2.7 ≤ x ≤ 3.3	2,9
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	100,0	Type II/Type IIR	3
Mask 2	100,0	Type II/Type IIR	4
Mask 3	100,0	Type II/Type IIR	5
Mask 4	99,6	Type II/Type IIR	6
Mask 5	100,0	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 requirementts 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

* 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)

** "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.

*** 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.

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

Test 2:

Test conditions

Analysis start date:	29-06-2020
Analysis start time:	15:30
Incubation conditions:	See table
Operator:	ESA

N° of mask	Weight (in g)
Mask 1	3,39
Mask 2	3,38
Mask 3	3,02
Mask 4	2,48
Mask 5	2,66

Medium Tryptone casein soy (TSA)					
Reference:	CASO/TSA	Lot number:	2980117	Exp. Date:	11-11-20
Incubation				Reading	
Temperature					
32.5°C ± 2.5°C	Incubation date:	29-06-2020		Reading date:	02-07-2020
Sabouraud + chloramphenicol medium					
Reference:	P05070A	Lot number:	4259160	Exp. Date:	14-10-20
Incubation				Reading	
Temperature					
22.5°C ± 2.5°C	Incubation date:	29-06-2020		Reading date:	06-07-2020

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

Test 2: Microbial cleanliness - Summary of the results obtained

Test results:

Mask number	Position in the box	Total bacterial flora		total fungal flora		Total flora		Correction factor **	Estimated bioburden	
		[CFU/g]	[CFU/mask]	[CFU/g]	[CFU/mask]	[CFU/g]	[CFU/mask]		[CFU/g]	[CFU/mask]
1	Above	6	22	3	11	10	32	1,1	11	36
2	Below	5	16	4	14	9	30	1,1	10	33
3	Mask 3 *	19	57	6	19	25	76	1,1	28	83
4	Mask 4 *	17	43	10	24	27	68	1,1	30	74
5	Mask 5 *	15	41	7	19	22	59	1,1	25	65

** Randomly sampled*
*** Factor determined during the evaluation of the efficiency of bioburden recovery in masks with the extraction method selected by HeX LAB*

Reference of the mask	Replicate	Result [CFU/g]	Compliance criteria in CFU/g	Status
UltraMask	Mask 1	11	≤ 30	Compliant
	Mask 2	10		Compliant
	Mask 3	28		Compliant
	Mask 4	30		Compliant
	Mask 5	25		Compliant

Average microbial cleanliness of this series of masks	20 [UFC/g]
Each mask meets the criteria	Oui

Global compliance status on 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 Filtrations Efficiency (BFE) [%]	≥ 95	≥ 98	≥ 98
Microbial cleanliness [cfu/g]	≤ 30	≤ 30	≤ 30

Type of mask claimed:	Microbial cleanliness target to obtain	Average microbial cleanliness for this series of masks	Each mask meets the criteria	Status
Type IIR	≤ 30 [CFU/g]	20 [UFC/g]	Oui	Compliant

* 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)

Status and decision rule: Measurement uncertainties are not taken into account in the declaration of conformity for the various tests.
HeX recalls the importance of verifying the information on the packaging on page 5 for the interpretation of the results

General comments

N/A

End of report

Report followed by Annex 1 giving the raw results of the various tests carried out

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Subcontracting to HeX Lab

Your laboratory expert
in analysing your critical process

positive test

Brand:	UltraMask
Reference:	EASM 198R
Expiration Date:	26-06-20
Serial number	N/A
Sample size:	N/A
Test date:	02 juillet 2020
Ambient temperature	N/A [°C]
Ambient relative humidity	N/A [%HR]

Flow during the test	positive test Start	Positive test End
	28,3 [l/min]	28,3 [l/min]

Inoculum

Microorganism of the tests:	Staphyloccus aureus DSM 346
Title of the start solution:	3x10^5 [CFU/ml]

Conditioning

Time of entry (conditioning)	N/A
Average T°C (conditioning)	N/A [°C]
Average HR (conditioning)	N/A [%HR]
Exit time (conditioning)	N/A

Test conditions

Culture medium for sampling	TSA 4N	Lot number:	452239
Reading date:	03 juillet 2020	Exp. date cult. medium:	03 octobre 2020

Test results:

	Positive test start	Positive test end	Average
	CFU per plate	CFU per plate	CFU per plate
Level 1	289	258	274
Level 2	399	297	348
Level 3	400	400	400
Level 4	400	400	400
Level 5	400	400	400
Level 6	312	400	356
Sum	2200	2155	2178 (C)

Mean Particle Size (MPS)	2,9 [µm]
Compliance criteria	(3,0 +/- 0,3 µm)
Verified condition APS	Yes
Average of the totals of the 2 positive tests (C)	2178 [CFU]
Compliance criteria	1700 ≤ x ≤ 3000
Verefied condition of value C	Yes

Formula used:

$$TMP = \frac{(P1 \times C1) + (P2 \times C2) + (P3 \times C3) + (P4 \times C4) + (P5 \times C5) + (P6 \times C6)}{C1 + C2 + C3 + C4 + C5 + C6}$$

Where : P1 = 7.00 [µm] P2 = 4.70 [µm] P3 = 3.30 [µm] P4 = 2.10 [µm] P5 = 1.10 [µm] P6 = 0.65 [µm]

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in analysing your critical process

Negative test

Brand:	UltraMask
Reference:	EASM 198R
Expiration Date:	26-06-20
Serial number	N/A
Sample size:	N/A
Test date:	02 juillet 2020
Ambient temperature	N/A [°C]
Ambient relative humidity	N/A [%HR]
Flow during the test	28,3 [l/min]

Inoculum

Microorganism of the tests:	Staphyloccus aureus DSM 346
Title of the start solution:	3x10^5 [CFU/ml]

Conditioning

Time of entry (conditioning)	N/A
Average T°C (conditioning)	N/A [°C]
Average HR (conditioning)	N/A [%HR]
Exit time (conditioning)	N/A

Test conditions

Culture medium for sampling	TSA 4N	Lot number:	452239
Reading date:	03 juillet 2020	Exp. date cult. medium:	03 octobre 2020

Test results:

	CFU per plate
Level 1	0
Level 2	0
Level 3	0
Level 4	0
Level 5	0
Level 6	0
Average	0 [CFU/Plate]
Compliance criteria	< 1 CFU
Verified condition check on the avarage of the negative test	Yes

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Mask 1

Brand:	UltraMask
Reference:	EASM 198R
Expiration Date:	26-06-20
Serial number	N/A
Sample size:	N/A
Test date:	02 juillet 2020
Ambient temperature	19 [°C]
Ambient relative humidity	55 [%HR]
Flow during the test	28,3 [l/min]

Inoculum

Microorganism of the tests:	Staphyloccus aureus DSM 346
Title of the start solution:	3x10^5 [CFU/ml]

Conditioning

Time of entry (conditioning)	13 h 00
Average T°C (conditioning)	20,5 [°C]
Average HR (conditioning)	85 [%HR]
Exit time (conditioning)	17 h 30

Test conditions

Culture medium for sampling	TSA 4N	Lot number:	452239
Reading date:	03 juillet 2020	Exp. date cult. medium:	03 octobre 2020

Witness results:

Average of the totals of the 2 positive tests (C)	2178 [CFU]

Test results:

	CFU per plate
Level 1	0
Level 2	0
Level 3	0
Level 4	0
Level 5	0
Level 6	0
Sum	0 [UFC]
Result of the Bacterial Filtration Efficiency (BFE) obtained	100 [%]

Formula used:

$$B = \frac{C - T}{C} \times 100$$

with :
B - Bacterial Filtration Efficiency (EFB)
C - Is the average of the colony count totals on the plates of the two positive control tests
T - Is the total of the colony count on plates for the sample

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Mask 2

Brand:	UltraMask
Reference:	EASM 198R
Expiration Date:	26-06-20
Serial number	N/A
Sample size:	N/A
Test date:	02 juillet 2020
Ambient temperature	19 [°C]
Ambient relative humidity	55 [%HR]
Flow during the test	28,3 [l/min]

Inoculum

Microorganism of the tests:	Staphyloccus aureus DSM 346
Title of the start solution:	3x10^5 [CFU/ml]

Conditioning

Time of entry (conditioning)	13 h 00
Average T°C (conditioning)	20,5 [°C]
Average HR (conditioning)	85 [%HR]
Exit time (conditioning)	17 h 30

Test conditions

Culture medium for sampling	TSA 4N	Lot number:	452239
Reading date:	03 juillet 2020	Exp. date cult. medium:	03 octobre 2020

Witness results:

Average of the totals of the 2 positive tests (C)	2178 [CFU]

Test results:

	CFU per plate
Level 1	0
Level 2	0
Level 3	0
Level 4	0
Level 5	0
Level 6	1
Sum	1 [UFC]
Result of the Bacterial Filtration Efficiency (BFE) obtained	100 [%]

Formula used:

$$B = \frac{C - T}{C} \times 100$$

with :
B - Bacterial Filtration Efficiency (EFB)
C - Is the average of the colony count totals on the plates of the two positive control tests
T - Is the total of the colony count on plates for the sample

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Mask 3

Brand:	UltraMask
Reference:	EASM 198R
Expiration Date:	26-06-20
Serial number	N/A
Sample size:	N/A
Test date:	02 juillet 2020
Ambient temperature	19 [°C]
Ambient relative humidity	55 [%HR]
Flow during the test	28,3 [l/min]

Inoculum

Microorganism of the tests:	Staphyloccus aureus DSM 346
Title of the start solution:	3x10^5 [CFU/ml]

Conditioning

Time of entry (conditioning)	13 h 00
Average T°C (conditioning)	20,5 [°C]
Average HR (conditioning)	85 [%HR]
Exit time (conditioning)	17 h 30

Test conditions

Culture medium for sampling	TSA 4N	Lot number:	452239
Reading date:	03 juillet 2020	Exp. date cult. medium:	03 octobre 2020

Witness results:

Average of the totals of the 2 positive tests (C)	2178 [CFU]

Test results:

	CFU per plate
Level 1	0
Level 2	0
Level 3	0
Level 4	0
Level 5	0
Level 6	1
Sum	1 [UFC]
Result of the Bacterial Filtration Efficiency (BFE) obtained	100 [%]

Formula used:

$$B = \frac{C - T}{C} \times 100$$

with :
B - Bacterial Filtration Efficiency (EFB)
C - Is the average of the colony count totals on the plates of the two positive control tests
T - Is the total of the colony count on plates for the sample

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in analysing your critical process

Mask 4

Brand:	UltraMask
Reference:	EASM 198R
Expiration Date:	26-06-20
Serial number	N/A
Sample size:	N/A
Test date:	02 juillet 2020
Ambient temperature	19 [°C]
Ambient relative humidity	55 [%HR]
Flow during the test	28,3 [l/min]

Inoculum

Microorganism of the tests:	Staphyloccus aureus DSM 346
Title of the start solution:	3x10^5 [CFU/ml]

Conditioning

Time of entry (conditioning)	13 h 00
Average T°C (conditioning)	20,5 [°C]
Average HR (conditioning)	85 [%HR]
Exit time (conditioning)	17 h 30

Test conditions

Culture medium for sampling	TSA 4N	Lot number:	452239
Reading date:	03 juillet 2020	Exp. date cult. medium:	03 octobre 2020

Witness results:

Average of the totals of the 2 positive tests (C)	2178 [CFU]

Test results:

	CFU per plate
Level 1	0
Level 2	0
Level 3	1
Level 4	0
Level 5	1
Level 6	7
Sum	9 [UFC]
Result of the Bacterial Filtration Efficiency (BFE) obtained	99,6 [%]

Formula used:

$$B = \frac{C - T}{C} \times 100$$

with :
B - Bacterial Filtration Efficiency (EFB)
C - Is the average of the colony count totals on the plates of the two positive control tests
T - Is the total of the colony count on plates for the sample

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Mask 5

Brand:	UltraMask
Reference:	EASM 198R
Expiration Date:	26-06-20
Serial number	N/A
Sample size:	N/A
Test date:	02 juillet 2020
Ambient temperature	19 [°C]
Ambient relative humidity	55 [%HR]
Flow during the test	28,3 [l/min]

Inoculum

Microorganism of the tests:	Staphyloccus aureus DSM 346
Title of the start solution:	3x10^5 [CFU/ml]

Conditioning

Time of entry (conditioning)	13 h 00
Average T°C (conditioning)	20,5 [°C]
Average HR (conditioning)	85 [%HR]
Exit time (conditioning)	17 h 30

Test conditions

Culture medium for sampling	TSA 4N	Lot number:	452239
Reading date:	03 juillet 2020	Exp. date cult. medium:	03 octobre 2020

Witness results:

Average of the totals of the 2 positive tests (C)	2178 [CFU]

Test results:

	CFU per plate
Level 1	1
Level 2	0
Level 3	0
Level 4	0
Level 5	0
Level 6	0
Sum	1 [UFC]
Result of the Bacterial Filtration Efficiency (BFE) obtained	100 [%]

Formula used:

$$B = \frac{C - T}{C} \times 100$$

with :
B - Bacterial Filtration Efficiency (EFB)
C - Is the average of the colony count totals on the plates of the two positive control tests
T - Is the total of the colony count on plates for the sample

Breathability test report (ΔP) on mask for medical use EN 14683 + AC: 2019 Annex C

of which included comparison with Alternative Test Protocol (ATP)

Client:	Ultrafilter GmbH Otto-Hahn-Strasse 1 40721 Hilden/ Germany
Group:	Ultrafilter GmbH
Client referent:	Mr Kronsbein
Site client:	Ultrafilter GmbH Otto-Hahn-Strasse 1 40721 Hilden/ Germany
Measurement location:	HeX - Hygiene & Expertise (Gosselies) Rue Auguste Piccard, 20 B-6041 Gosselies

CBE registration number: *(Information given by the client)*	N/A
Air Waybill (AWB): *(Information given by the client)*	N/A
Customs file number: *(Information given by the client)*	N/A

FI identification number:	200877
Report identification number:	ULTRA01-2-01-200519-1_PDIFF-MC
Report version :	1
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Number of pages report:	7

test required according to :	EN14683+AC :2019_Annex C
Operation mode:	7.2 Exe-Mo43
Operator(s):	Quentin Destexhe
Report edited by:	Quentin Destexhe

Reviewed and Approved by:

Foreword & Context (1/2)

EN 14683+AC:2019

EN 14683 + AC: 2019 specifies the requirements and test methods for medical masks.
This report only provides the results of the breathability determination (ΔP) test in accordance with Annex C of the standard.

Mask for medical use : medical device covering the mouth and nose, which constitutes a barrier making it possible to minimize the direct transmission of infectious agents between the medical team and the patient

Differential pressure : air permeability of the mask, measured by determining the pressure difference across the mask under specific conditions of air flow, temperature and humidity

Bacterial filtration efficiency (BFE) : effectiveness of the materials making up the mask for medical use as a barrier against bacterial penetration

Resistance to projections : capacity of a mask for medical use to resist the penetration of synthetic blood projected at a given pressure.

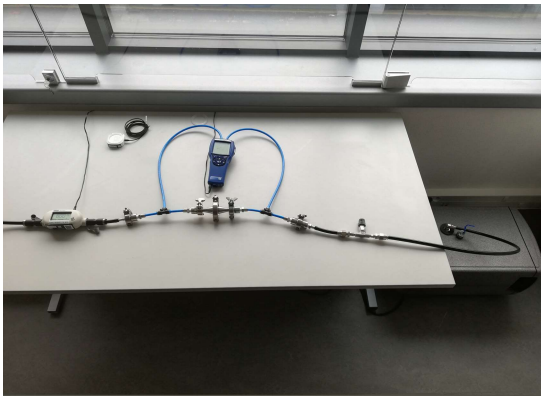
Classification
Masks for medical use are classified into two types (I and II) according to the bacterial filtration efficiency (BFE), after which an additional subdivision is made for type II according to whether or not it is resistant to projections. The letter "R" indicates resistance to projections.
This test report makes it possible to distinguish the type of mask as a function of the differential pressure result in Pa / cm². The compliance status is therefore established by HeX based on the results obtained and the performance requirements of the type of mask for medical use announced by the client. (see table below)

Table of performance requirements for medical masks (§5.2.7 EN14683 + 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

* Type I medical masks should only be used for patients and others to reduce the risk of spreading infection, especially during 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.

Test bench (photograph)



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Foreword & Context (continued 2/2)

Alternative Test Protocol (ATP)

The COVID-19 outbreak is hampering the supply of various health materials, including medical devices such as surgical masks. Many of the proposed surgical masks do not have the necessary declarations, certificates and test reports to unequivocally demonstrate that they meet the requirements of the applicable European standard (EN 14683:2019 + AC:2019) or one of the international standards that are currently also accepted on an exceptional basis (ASTM F2100, YY 0469:2011 and YY/T 0969-2013). In normal circumstances, these masks would not be put into service, as their quality and efficiency cannot be guaranteed. Due to the high demand in this crisis situation and in order to reduce the large shortages of masks, the FAMHP (the Belgian medicines agency) acknowledges that these masks can be subjected to a simplified test protocol, the ATP, which only takes into account the test results of two important parameters: the efficiency of the bacterial filtration (BFE) and the differential pressure (ΔP).

HeX recalls that this test is part of the ATP protocol according to the note of the FAMHP of 20/04/2020 (Information on the alternative test protocol "Alternative Test Protocol, ATP" for surgical mouth masks). HeX is in the process of applying for accreditation. During this time, the results obtained are not taken into account by the FAMHP / FAGG and only the FAMHP can allow a derogation from the marketing requirements for medical devices. HeX informs you that at the request of the authorities, HeX may be required to disclose confidential information, such as test reports.

The tests are carried out as follows: first the differential pressure (ΔP) (Pa/cm²) is tested. Depending on the result of this test, further tests are carried out as follows:

- If ΔP <25 Pa: there is a small chance (<30%) that the BFE test will give a favorable result (BFE ≥ 95%). If the importer / supplier of the masks wishes, the BFE test will always be carried out.
  - If the BFE is ≥ 95%: the masks are considered to be “ATP equivalent”, they can be sold as surgical masks according to ATP conditions.
  - If the BFE is <95%: the masks are considered to be "ATP equivalent".
  - BFE ≥ 70%: the masks can be sold as comfort masks according to ATP conditions and after affixing a label.
  - If the BFE <70%: the masks cannot be sold.
  - If no BFE test is carried out by the importer after the Delta P test, the masks are assumed to have a BFE <70% and cannot be sold.

- If 25 Pa ≤ ΔP <35 Pa: there is little correlation between ΔP and BFE in this range. It is therefore highly recommended to also test the BFE here.
  - If the BFE is ≥ 95%: the masks are considered to be “ATP equivalent”, they can be sold as surgical masks according to ATP conditions.
  - If the BFE is <95%: the masks are considered to be "ATP equivalent".
  - BFE ≥ 70%: the masks can be sold as comfort masks according to ATP conditions and after affixing a label.
  - BFE <70%: masks cannot be sold.
  - If no BFE test is carried out by the importer after the ΔP test, the masks are assumed to have a BFE <70% and cannot be sold.

- If 35 Pa ≤ ΔP ≤ 65 Pa: within this range, it is sufficiently certain that the masks will have a BFE ≥ 95% (and probably ≥ 98%). The BFE is no longer tested in this case and the masks can be marketed as surgical masks.

The status of compliance under the ATP is given merely as an indication and only engages the responsibility of the client to follow these recommendations:

- Colour code Green:
Values obtained = If ΔP between 35 and 65 Pa
Status: compliant surgical mask under the ATP

- Colour code Orange :
Values obtained = If ΔP between 25 et 35 Pa
Status: non-compliant surgical mask under the ATP unless a BFE test is carried out and the status of this test is compliant (but this BFE test is not carried out by HeX; the mask will have to be sent to a competent laboratory such as Centexbel in Belgium).

- Colour code Red:
Values obtained = If ΔP < 25 Pa
Status: non-compliant surgical mask under the ATP unless a BFE test is carried out and the status of this test is compliant (but this BFE test is not carried out by HeX; the mask will have to be sent to a competent laboratory such as Centexbel in Belgium).

HeX would like to point out that the efficiency of a surgical type mask is characterized by meeting a set of requirements. If the result of this Differential Pressure test is compliant, HeX recalls that extrapolation to overall mask compliance in accordance with the requirements of EN 14683+ AC:2019 is not required. For this reason, the ATP protocol is used to secure the decision making process.

<u>Client responsibilities and requirements:</u>
The following points have to be respected by the client throughout the study:
- Masks of the same brand, same model
- Supply of a certain quantity of masks and in accordance with the associated offer
- The masks will be sent at the client's expense and under his responsibility
- Strict compliance with traceability and nomenclature conditions as well as filling in the traceability and linkage sheet associated with the package.

Document information

Version: 1.08

Version date: 20 May 2020

Version reviewed and validated by: David Deneuville – Technical Manager

Validity of the report: Only the latest electronic version available on the server is deemed authentic.
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Confidentiality: All information related to the knowledge of the installations as well as any document, plan and file element given by the client will be kept confidential. The results of the report may not be communicated to third parties (except with the written agreement of the client).

Revision: The signed final report cancels all communicated interim results and documents. Each revision cancels and replaces the previous one. Any outdated version must be destroyed as well as any copie that may have been made. We draw your attention to the risk of errors in keeping an outdated version.

Decision rule: Measurement uncertainties are not taken into account in the declaration of compliance of the different tests.

Accreditation & AFMPS : HeX is in the process of applying for accreditation in accordance with the ISO 17025 requirements by BELAC. In the meantime, the results obtained are not taken into account by the FAMHP/FAGG and only the FAMHP can allow a derogation from the marketing requirements for medical devices.
HeX informs you that on simple request of the authorities, HeX may be required to disclose confidential information, such as test reports.

Used measuring equipment

Type	Reference	Serial number	Due Date
Vacuum pump	Becker VT4.16	3297878	01 February 2021
Electronic manometer	TSI S565-P	P1433013	07 July 2020
Flowmeter no. 1 (Upstream)	TSI4043 H	40431848006	28 November 2020
Filter holder	Reduction conc. 316 L poli ASME BPE	EN 10204/3.1	01 February 2021
Humidity generator (packaging)	GH500	4F170114218	13 February 2022
RH sensor (packaging)	ENG 01	N/A	06 May 2021
Temperature sensor (packaging)	ENG 01	N/A	06 May 2021

Your expert in contamination control

Test summary :

Brand:	Ultrafilter GmbH
Reference:	Ultramask
Efficiency:	Surgical Mask
Use-by date:	N/A
Flow direction:	From inside to outside of the mask
Sampled surface:	5x 4.9 cm² (diameter of 25+-1 cm / 8liter per min)
Packaging of the sample:	min 4h30 at 21 ± 5 [°C] and 85 ± 5 [%RH]

Differential pressure / Breathability [Pa/cm²]

Test reference:	Mask:	Average differential pressure [Pa/cm²] :	Raw data cf. Annex 1 Page:
Réf0 M1	M1	49.5	1
Réf0 M2	M2	53.3	2
Réf0 M3	M3	53.0	3
Réf0 M4	M4	53.4	4
Réf0 M5	M5	50.0	5

Average of differential pressure masks [Pa/cm²] 51.8

Global compliance status according to EN 14683 + AC: 2019

Category (ies) assigned according to the performance requirements of EN 14683 + AC: 2019 (Without AQL **)

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 AQL criterion **	Compliance status WITHOUT AQL criteria **
51.8 [Pa/cm²]	Type IIR	96 [%]	92 [%]		Non-compliant	Compliant

* 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)

** "*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.

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

Your expert in contamination control

Differential pressure / Breathability [Pa/cm²]*

Criteria following the ATP protocol for surgical masks

Reference average [Pa/cm²]	Criterion category	Colour code	Status
51.8	35 ≤ ΔP < 65	Green	in this range, it is sufficiently certain that the masks will have a BFE ≥ 95% (and probably ≥ 98%). The BFE is no longer tested in this case and the masks can be marketed as surgical masks.

Reminder on the different categories of criteria:

- If ΔP <25 Pa: there is a small chance (<30%) that the BFE test will give a favorable result (BFE ≥ 95%). If the importer / supplier of the masks wishes, the BFE test will always be performed.
  - If the BFE is ≥ 95%: the masks are considered to be “ATP equivalent”, they can be sold as surgical masks according to ATP conditions.
  - If the BFE is <95%: the masks are considered to be "ATP equivalent".
  - BFE ≥ 70%: the masks can be sold as comfort masks according to ATP conditions and after affixing a label.
  - If the BFE <70%: the masks cannot be sold.
  - If no BFE test is carried out by the importer after the Delta P test, the masks are assumed to have a BFE <70% and cannot be sold. "

- If 25 Pa ≤ ΔP <35 Pa: there is little correlation between ΔP and BFE in this range. It is therefore strongly recommended to also test BFE here.
  - If the BFE is ≥ 95%: the masks are considered to be “ATP equivalent”, they can be sold as surgical masks according to ATP conditions.
  - If the BFE is <95%: the masks are considered to be "ATP equivalent".
  - BFE ≥ 70%: the masks can be sold as comfort masks according to ATP conditions and after affixing a label.
  - BFE <70%: masks cannot be sold.
  - If no BFE test is carried out by the importer after the ΔP test, the masks are assumed to have a BFE <70% and cannot be sold.

- If 35 Pa ≤ ΔP ≤ 65 Pa: within this range, it is sufficiently certain that the masks will have a BFE ≥ 95% (and probably ≥ 98%). The BFE is no longer tested in this case and the masks can be marketed as surgical masks.

* 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)

HeX recalls that the efficiency of a surgical type mask is characterized by meeting a set of requirements. If this differential pressure test is compliant, HeX recalls that extrapolation to overall mask compliance according to the requirements of EN 14683+ AC:2019 is not required. For this reason, the ATP protocol is used to secure the decision making process.

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

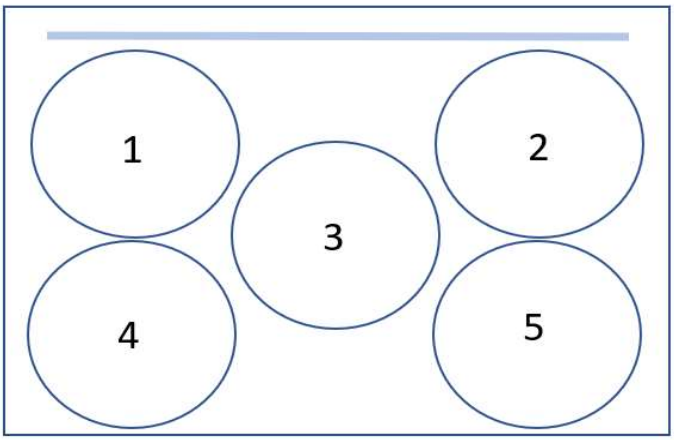
HeX is in the process of applying for accreditation in accordance with the ISO 17025 requirements by BELAC. In the meantime, the results obtained are not taken into account by the FAMHP/FAGG and only the FAMHP can allow a derogation from the marketing requirements for medical devices. HeX informs you that on simple request of the authorities, HeX may be required to disclose confidential information, such as test reports.

Photographs of the test object

Packaging :

Mask :

Schematic distribution of samples taken by mask *



Caption :

(Metal) Nasal adjustment

Sample taken

*Non-contractual diagram given as an indication

General comment

N/A

End of report

Report followed by Annex 1 giving the raw results of the various tests carried out

Your expert in contamination control

Test : Réf0 M1

Brand:	Ultrafilter GmbH
Reference:	Ultramask
Type:	Surgical Mask
Use-by date:	N/A
Serial number:	N/A
Date of measurement:	19 mai 2020
Ambient temperature:	25.6 [°C]
Ambient relative humidity:	40.7 [%HR]
Sampled surface:	4.9 cm²
Coefficient reference surface:	4.90

Pre-measurement verifications

Leak check of assembly:	Effectué
Upstream flow:	8 [l/min]
ΔP (ref) without filter:	42 [Pa]

Packaging

Time of entry (packaging):	8 h 45
Average T°C (packaging):	23.19 [°C]
Average RH (packaging):	87.7 [%RH]
Time of exit (packaging):	13 h 40

Measurement results

Measured ΔP (E1):	278 [Pa]	
Measured ΔP (E2):	273.9 [Pa]	
Measured ΔP (E3):	339 [Pa]	
Measured ΔP (E4):	280.4 [Pa]	
Measured ΔP (E5):	250.8 [Pa]	
Calculated ΔP (E1):	48.2 [Pa/cm²]	
Calculated ΔP (E2):	47.3 [Pa/cm²]	
Calculated ΔP (E3):	60.6 [Pa/cm²]	AQL***
Calculated ΔP (E4):	48.7 [Pa/cm²]	
Calculated ΔP (E5):	42.6 [Pa/cm²]	

Average differential pressure [Pa/cm²] :	**49.5 [Pa/cm²]**

Your expert in contamination control

Test : Réf0 M2

Brand:	Ultrafilter GmbH
Reference:	Ultramask
Type:	Surgical Mask
Use-by date:	N/A
Serial number:	N/A
Date of measurement:	19 mai 2020
Ambient temperature:	25.6 [°C]
Ambient relative humidity:	40.7 [%HR]
Sampled surface:	4.9 cm²
Coefficient reference surface:	4.90

Pre-measurement verifications

Leak check of assembly:	Effectué
Upstream flow:	8 [l/min]
ΔP (ref) without filter:	42.1 [Pa]

Packaging

Time of entry (packaging):	8 h 45
Average T°C (packaging):	23.19 [°C]
Average RH (packaging):	87.7 [%RH]
Time of exit (packaging):	13 h 40

Measurement results

Measured ΔP (E1):	289.4 [Pa]
Measured ΔP (E2):	333 [Pa]
Measured ΔP (E3):	319.4 [Pa]
Measured ΔP (E4):	312.9 [Pa]
Measured ΔP (E5):	261.2 [Pa]
Calculated ΔP (E1):	50.5 [Pa/cm²]
Calculated ΔP (E2):	59.4 [Pa/cm²]
Calculated ΔP (E3):	56.6 [Pa/cm²]
Calculated ΔP (E4):	55.3 [Pa/cm²]
Calculated ΔP (E5):	44.7 [Pa/cm²]

Average differential pressure [Pa/cm²] :	**53.3 [Pa/cm²]**

Your expert in contamination control

Test : Réf0 M3

Brand:	Ultrafilter GmbH
Reference:	Ultramask
Type:	Surgical Mask
Use-by date:	N/A
Serial number:	N/A
Date of measurement:	19 mai 2020
Ambient temperature:	25.6 [°C]
Ambient relative humidity:	40.7 [%HR]
Sampled surface:	4.9 cm²
Coefficient reference surface:	4.90

Pre-measurement verifications

Leak check of assembly:	Effectué
Upstream flow:	8 [l/min]
ΔP (ref) without filter:	42.3 [Pa]

Packaging

Time of entry (packaging):	8 h 45
Average T°C (packaging):	23.19 [°C]
Average RH (packaging):	87.7 [%RH]
Time of exit (packaging):	13 h 40

Measurement results

Measured ΔP (E1):	280.6 [Pa]
Measured ΔP (E2):	275 [Pa]
Measured ΔP (E3):	322.8 [Pa]
Measured ΔP (E4):	300.3 [Pa]
Measured ΔP (E5):	332 [Pa]
Calculated ΔP (E1):	48.6 [Pa/cm²]
Calculated ΔP (E2):	47.5 [Pa/cm²]
Calculated ΔP (E3):	57.2 [Pa/cm²]
Calculated ΔP (E4):	52.7 [Pa/cm²]
Calculated ΔP (E5):	59.1 [Pa/cm²]

Average differential pressure [Pa/cm²] :	**53 [Pa/cm²]**

Your expert in contamination control

Test : Réf0 M4

Brand:	Ultrafilter GmbH
Reference:	Ultramask
Type:	Surgical Mask
Use-by date:	N/A
Serial number:	N/A
Date of measurement:	19 mai 2020
Ambient temperature:	25.6 [°C]
Ambient relative humidity:	40.7 [%HR]
Sampled surface:	4.9 cm²
Coefficient reference surface:	4.90

Pre-measurement verifications

Leak check of assembly:	Effectué
Upstream flow:	8 [l/min]
ΔP (ref) without filter:	42.3 [Pa]

Packaging

Time of entry (packaging):	8 h 45
Average T°C (packaging):	23.19 [°C]
Average RH (packaging):	87.7 [%RH]
Time of exit (packaging):	13 h 40

Measurement results

Measured ΔP (E1):	299 [Pa]
Measured ΔP (E2):	270.5 [Pa]
Measured ΔP (E3):	329.1 [Pa]
Measured ΔP (E4):	289.7 [Pa]
Measured ΔP (E5):	331.1 [Pa]
Calculated ΔP (E1):	52.4 [Pa/cm²]
Calculated ΔP (E2):	46.6 [Pa/cm²]
Calculated ΔP (E3):	58.5 [Pa/cm²]
Calculated ΔP (E4):	50.5 [Pa/cm²]
Calculated ΔP (E5):	58.9 [Pa/cm²]

Average differential pressure [Pa/cm²] :	**53.4 [Pa/cm²]**

Your expert in contamination control

Test : Réf0 M5

Brand:	Ultrafilter GmbH
Reference:	Ultramask
Type:	Surgical Mask
Use-by date:	N/A
Serial number:	N/A
Date of measurement:	19 mai 2020
Ambient temperature:	25.6 [°C]
Ambient relative humidity:	40.7 [%HR]
Sampled surface:	4.9 cm²
Coefficient reference surface:	4.90

Pre-measurement verifications

Leak check of assembly:	Effectué
Upstream flow:	8 [l/min]
ΔP (ref) without filter:	42.4 [Pa]

Packaging

Time of entry (packaging):	8 h 45
Average T°C (packaging):	23.19 [°C]
Average RH (packaging):	87.7 [%RH]
Time of exit (packaging):	13 h 40

Measurement results

Measured ΔP (E1):	283.4 [Pa]	
Measured ΔP (E2):	277 [Pa]	
Measured ΔP (E3):	342 [Pa]	
Measured ΔP (E4):	278 [Pa]	
Measured ΔP (E5):	256.7 [Pa]	
Calculated ΔP (E1):	49.2 [Pa/cm²]	
Calculated ΔP (E2):	47.9 [Pa/cm²]	
Calculated ΔP (E3):	61.1 [Pa/cm²]	AQL***
Calculated ΔP (E4):	48.1 [Pa/cm²]	
Calculated ΔP (E5):	43.7 [Pa/cm²]	

Average differential pressure [Pa/cm²] :	**50 [Pa/cm²]**