



[Faded text, likely contact information for the laboratory]



Your notice of 11-09-2012 Your reference 196YR2012 Date 09-10-2012

Analysis Report 12.03884.02

Required tests :

EN 13795 (2011)	ISO 22610 (2006)	Resistance to wet microbial penetration
EN 13795 (2011)	ISO 22612 (2005)	Resistance to dry microbial penetration
EN 13795 (2011)	EN ISO 11737-1 (2006)	Microbial cleanliness
EN 13795 (2011)	ISO 9073-10 (2003)	Linting and cleanliness- particulate matter
EN 13795 (2011)	EN 20811 (1992)	Determination of the resistance to water penetration - Method of hydrostatic pressure
EN 13795 (2011)	EN 29073-3 (1992)	Determination of the breaking strength and elongation of non-woven
EN 13795 (2011)	ISO 13938-1 (1999)	Determination of the bursting strength

Identification number	Information given by the client	Date of receipt
T1212527	35 g/m ² SMMS in blue - non sterile	10-09-2012

VAT BE 0459.218.289 Fin. Acc. 210-0472965-45 IBAN BE44 2100 4729 6545

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INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ÉTABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTÉ-LOI DU 30 JANVIER 1947



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Yvette Rogister

Order responsible

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The results of the analysis cover the received samples. Centexbel is not responsible for the representativeness of the samples. In assessing compliance with the specifications, we did not take into account the uncertainty on the test results.

INRICHTING ERKENDE BIJ TOEPASSING VAN DE BESLUITWIJZING VAN 30 JANUARI 1947 / ÉTABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTÉ-LOI DU 30 JANVIER 1947

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Reference: T1212527 - 35 g/m² SMMS in blue - non sterile

Resistance to wet microbial penetration

Date of ending the test	21-09-2012
Standard used	ISO 22610 (2006)
Product standard	EN 13795 (2011)
Type of sample	Blue non woven - non sterile
Dimension of the test specimens	25 x 25 cm ²
Number of test specimens	5
Sampling	At random in the received piece of non woven
Test specimens conditioning	None
Covering material	HDPE film
Donor material	Polyurethane film, supplied by Schütt Labortechnik
Side in contact with the bacteria	Inner side
Inoculum titre (CFU/ml)	1- 4 10 ⁴ CFU/ml
Bacterial strain	<i>Staphylococcus aureus</i> ATCC29213
Distance agar - plate rim	± 3 mm
Number of plates/test	5
Test conditions	Room conditions
Incubation time	24 to 48 hours
Incubation temperature	37 ± 2°C
Colonies count	The colonies are enumerated on the periphery of the agar surface of the plate, by excluding the 30 mm diameter centre
Calibration	60 rpm agar plate rotation 11 mm radius finger 3N force on finger Carbon paper for contact pattern control
Deviation from the standard	Test specimens sterilisation by ethylene oxide



Results

	Test specimen #1	Test specimen #2	Test specimen #3	Test specimen #4	Test specimen #5
	CFU/plate	CFU/plate	CFU/plate	CFU/plate	CFU/plate
Plate 1 (15 min)	488	234	537	604	394
Plate 2 (30 min)	307	182	221	480	259
Plate 3 (45 min)	299	168	207	417	195
Plate 4 (60 min)	212	147	234	376	197
Plate 5 (75 min)	214	119	207	203	203
Plate 6 (test specimen alone)	97	89	125	212	125
Inoculum titre (CFU/ml)	1 10 ⁴	1 10 ⁴	1 10 ⁴	1 10 ⁴	1 10 ⁴
C _{BP}	2.9	2.8	3.0	2.9	2.9
Barrier index (I _B)	2.8	3.0	2.8	2.9	2.9
R _{CUM5}	0.9	0.9	0.9	0.9	0.9

	Mean	Standard deviation
C _{BP}	2.9	0.1
Barrier index (I _B)	2.9	0.1
R _{CUM5}	0.9	0.0

Annex 1

Method description

Performed in the microbiological lab under the responsibility of Yvette Rogister



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Reference: T1212527 - 35 g/m² SMMS in blue - non sterile

Resistance to dry microbial penetration

Date of ending the test	24-09-2012
Standard used	ISO 22612 (2005)
Product standard	EN 13795 (2011)
Type of sample	Blue non woven - non sterile
Dimension of the test specimens	20 x 20 cm ²
Number of test specimens	12 (2 tests of 5 test specimens + 1 test specimen as control)
Sampling	At random in the received piece of non woven
Test specimens conditioning	20 ± 2°C and 65 ± 5°C RH
Conditioning time	24 hours The sample is not tested in conditioned area but directly after conditioning.
Sterilization	Ethylene oxide
Side in contact with the contaminated talc	Inner side
Talc contaminant	<i>Bacillus atrophaeus</i> spores ATCC 9372 (deposited as <i>Bacillus subtilis</i> var. niger at ATCC)
Talc count	± 10 ⁸ CFU/g
Test time (vibration)	30 minutes



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Results

	Run 1	Run 2
	CFU/plate	CFU/plate
Control	0	0
Test specimen#1	0	1
Test specimen#2	1	0
Test specimen#3	0	0
Test specimen#4	0	0
Test specimen#5	2	1

Arithmetic mean (CFU/plate)	1
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Annex 2

Method description

Performed in the microbiological lab under the responsibility of Yvette Rogister



Reference: T1212527 - 35 g/m² SMMS in blue - non sterile

Microbial cleanliness

Date of ending the test	24-09-2012
Standard used	EN ISO 11737-1 (2006)
Product standard	EN 13795 (2011)
Dimension of the test specimens	20 x 20 cm ²
Number of test specimens	3
Sampling	At random in the received piece of non woven
Extraction liquid	Peptone 1g/l, NaCl 5g/l & Tween 20 2g/l
Extraction volume	100 ml
Extraction time	30 sec.
Counting technique	Membrane filtration
Filtration volume	25ml
Culture medium	Plate Count Agar
Incubation temperature	30°C
Incubation time	72 hours

Results

Test specimen	CFU/100cm ²
#1	9
#2	10
#3	11
Mean CFU/100cm²	10

Annex 3

Method description

Performed in the microbiological lab under the responsibility of Yvette Rogister



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Reference: T1212527 - 35 g/m² SMMS in blue - non sterile

Linting and cleanliness- particulate matter

Date of ending the test	21-09-2012
Standard used	ISO 9073-10 (2003)
Product standard	EN 13795 (2011)
Type of sample	Blue non woven - non sterile
Dimension of the test specimens	220x285 mm (\pm 1 mm) The maximum length cut in the cross direction
Number of test specimens	5/side
Side A	Outer side
Side B	Inner side
Sampling	At random in the received piece of non woven
Apparatus	Gelboflex and particles counter
Gelboflex characteristics	Antistatic box Movement = 60 cycles/min 188 \pm 2 mm between the circular plates at the beginning of the test
Particles counter characteristics	LIGHTHOUSE Solair II 3100+ Flow = 28 L/min Channels: 0.5-1-2-3-4-5-7-10 μ m
Test conditions	ISO 5 class



Results

1) *Linting*

Particules count $\geq 3\mu\text{m}$ (according to EN13795)

	Side A	Side B
Test specimen #1	147	68
Test specimen #2	113	226
Test specimen #3	273	215
Test specimen #4	241	89
Test specimen #5	154	100
Linting (Mean)	186	140
Standard deviation	68	75
Coefficient of variation	36.6	53.6
Coefficient of linting (C_L)	2.3	2.1

$$C_L = \text{Log}_{10} \text{Linting}$$

Total Linting (Mean of both sides)	163
Coefficient of linting (C_L)	2.2



2) Cleanliness particulate matter

Particules count $\geq 3\mu\text{m}$ (according to EN13795)

	Side A	Side B
Test specimen #1	39	20
Test specimen #2	32	41
Test specimen #3	34	41
Test specimen #4	51	12
Test specimen #5	38	30
Total particulate matter (Mean)	39	29
Standard deviation	7.4	12.8
Coefficient of variation	19.1	44.6
Index particulate matter (IPM)	1.6	1.5

IPM = Log_{10} Particulate matter

Total particulate matter (Mean of both sides)	34
Index particulate matter (IPM)	1.5

Annex 4

Individual results

Annex 5

Method description

Performed in the microbiological lab under the responsibility of Yvette Rogister



Reference: T1212527 - 35 g/m² SMMS in blue - non sterile

Determination of the resistance to water penetration - Method of hydrostatic pressure

Date of ending the test 21-09-2012
Standard used EN 20811 (1992)
Product standard EN 13795 (2011)

Conditioning 20°C, relative humidity 65%
Deviation from the standard The test hasn't been carried out in the standard atmosphere but as soon as possible after conditioning

Apparatus Textest FX 3300
Assessment Penetrable at third spot
Number of test specimens 5
Water temperature 20 °C
Rate of pressure increase 10 mbar
Tested side Outer side

Test specimen	Water column
#1	64.5
#2	55.5
#3	58.5
#4	60.0
#5	69.5
Average (mbar)	61.5 mbar
Average(± cm)	± 61.5 cm

Performed under accreditation in the physical lab under the responsibility of Willy Vande Wiele

Reference: T1212527 - 35 g/m² SMMS in blue - non sterileDetermination of the breaking strength and elongation of non-woven

Date of ending the test 02-10-2012
Standard used EN 29073-3 (1992)
Product standard EN 13795 (2011)

Deviation from the standard -
Conditioning 20°C, relative humidity 65%
Wet specimens are humidified with 1g/nekanil

Apparatus Instron, type CRE, class 0,5
Cell 100 N (Length direction)
100 N (Width direction)

Clamps sheeting Covered with rubber
Rate 100 mm/min
Number of test specimens 5 (Length direction)
5 (Width direction)

Gauge length 200 mm
Width Cut, 50 mm

Conditioned

Specimen	Length direction		Width direction	
	Force (N)	Elongation (%)	Force (N)	Elongation (%)
#1	78.5	113	30.6	78
#2	75.1	108	22.7	52
#3	74.9	104	30.9	90
#4	59.0	56	28.7	75
#5	72.0	101	30.4	85
Average	71.9 N	96 %	28.7 N	76 %



Wet

Specimen	Length direction		Width direction	
	Force (N)	Elongation (%)	Force (N)	Elongation (%)
#1	79.1	104	29.5	68
#2	54.3	36.0	30.2*	84*
#3	71.1	91	30.2	70
#4	69.9	90	30.1	66
#5	74.4	90	30.8	74
Average	69.8 N	82 %	30.2 N	72.0 %

Remark: * = Specimen breaks at the edge of the jaws (the clamp breakings are mentioned but not rejected)

Performed in the physical lab under the responsibility of Willy Vande Wiele



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Reference: T1212527 - 35 g/m² SMMS in blue - non sterile

Determination of the bursting strength

Date of ending the test	21-09-2012
Standard used	ISO 13938-1 (1999)
Product standard	EN 13795 (2011)
Performed in an external lab	Celabor scrl Zoning de Petit Rechain
Annex 6	Report_21521.pdf

Centexbel is not responsible for the test results

Performed in an external lab