

# CERTIFICATE

## The company

is granted authorisation according to STANDARD 100 by OEKO-TEX® to use the STANDARD 100 by OEKO-TEX® mark, based on our test report 20200K0050



## for the following articles:

Woven fabrics made of 100% cotton, cotton/ elastane, polyester/ cotton, polyamide 6.6 (cordura), polyamide 6.6 (cordura)/ cotton, recycle polyester/ cotton, recycle polyester/ Organic cotton, cotton/ Nega-stat (R) and polyester/ cotton/ Nega-stat (R), greige, PFGD, white, dyed (reactive, vat, acid, disperse), coated (acrylic, PU) and finished; Woven fabrics made of 100% cotton, cotton/ elastane and polyester/ cotton pigment printed; Partly treated with teflon and finished with or without water and oil repellent. Woven fabrics made of Tencel/polyester and Polyester/ cotton stretch fabrics with T400 fibers High Visibility (yellow, red, orange). Partly based on pre-certified material according to STANDARD 100 by OEKO-TEX®. Finished with active chemical products accepted by STANDARD 100 by OEKO-TEX®

The results of the inspection made according to STANDARD 100 by OEKO-TEX®, Appendix 4, **product class II** have shown that the above mentioned goods meet the human-ecological requirements of the STANDARD 100 by OEKO-TEX® presently established in Appendix 4 for products with direct contact to skin.

The certified articles fulfill requirements of Annex XVII of REACH (incl. the use of azo colourants, nickel release, etc.), the American requirement regarding total content of lead in children's articles (CPSIA; with the exception of accessories made from glass) and of the Chinese standard GB 18401:2010 (labelling requirements were not verified).

The holder of the certificate, who has issued a conformity declaration according to ISO 17050-1, is under an obligation to use the STANDARD 100 by OEKO-TEX® mark only in conjunction with products that conform with the sample initially tested. The conformity is verified by audits.

**The certificate 2011PK0137 is valid until 30.11.2020**

Alcoy, 26.02.2020

Silvia Devesa Valencia  
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Isabel Soriano Sarrió  
Chief of Innovation Area



## EN 14683:2005 Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article: AntiVirus - Respilon  
 Laboratory Number: 754321  
 Study Received Date: 05 May 2014  
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 10

**Summary:** The BFE test is performed to determine the filtration efficiency by comparing the bacterial control counts to test article effluent counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. The Delta P test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. Testing was conducted as directed in Annex B (BFE testing) and Annex C (Delta P testing) of EN 14683:2005. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Sponsor Labeled Side  
 BFE Area Tested: ~45.6 cm<sup>2</sup>  
 BFE Flow Rate: 28.3 Liters per minute (L/min)  
 Delta P Flow Rate: 8 Liters per minute (L/min)  
 Conditioning Parameters: 65 ± 2% relative humidity (RH) and 20 ± 2°C

**Results:** Test articles with a filtration efficiency greater than or equal to 95% meet the performance requirements of EN 14683:2005 as Type I and/or Type IR. Test articles with a filtration efficiency greater than or equal to 98% meet the performance requirements of EN 14683:2005 as Type II and/or Type IIR.

Test articles with a differential pressure less than 29.4 pascals (Pa)/cm<sup>2</sup> meet the performance requirements of EN 14683:2005 as Type I and/or Type II. Test articles with a differential pressure less than 49.0 Pa/cm<sup>2</sup> meet the performance requirements of EN 14683:2005 as Type IR and/or Type IIR.

Test Article Number	Percent BFE (%)	Delta P (Pa/cm <sup>2</sup> )
1	>99.9 <sup>a</sup>	46.7
2	99.9	48.8
3	99.9	43.5
4	99.9	46.8
5	99.9	43.8

<sup>a</sup> There were no detected colonies on any of the Andersen sampler plates for this test article.

Mean Positive Control Count: 1,945 colony forming units (CFU)  
 Negative Monitor Count: <1 CFU  
 Mean Particle Size (MPS): 2.9 µm  
 Test Article Dimensions: ~210 mm x ~210 mm

  
 Study Director

Sarah Smit, B.S.

13 May 2014  
 Study Completion Date

## Latex Particle Challenge Final Report

Test Article: AntiVirus - Respilon  
 Laboratory Number: 754319  
 Study Received Date: 05 May 2014  
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0005 Rev 03

**Summary:** This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized, dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the average number of particles penetrating the test article compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Sponsor Labeled Side  
 Area Tested: 91.5 cm<sup>2</sup>  
 Particle Size: 0.1 µm  
 Laboratory Conditions: 20°C, 26%relative humidity (RH) at 0925; 20°C, 25%RH at 1025  
 Average Filtration Efficiency: 99.5%  
 Standard Deviation: 0.38

**Results:**

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	129	10,260	99.7
2	116	11,840	99.9
3	119	12,880	99.9
4	140	12,937	98.9
5	245	13,150	99.1

  
 Study Director Brandon L. Williams

  
 Study Completion Date

## Viral Filtration Efficiency (VFE) Final Report

Test Article: AntiVirus - Respilon  
 Laboratory Number: 754320  
 Study Received Date: 05 May 2014  
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0007 Rev 09

**Summary:** The VFE test is performed to determine the filtration efficiency by comparing the viral control counts to test article effluent counts. A suspension of bacteriophage  $\Phi$ X174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This method allows a reproducible challenge to be delivered to the test articles. The VFE test procedure was adapted from ASTM F2101. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Sponsor Labeled Side  
 Area Tested: ~45.6 cm<sup>2</sup>  
 VFE Flow Rate: 28.3 Liters per minute (L/min)

**Results:**

Test Article Number	Percent VFE (%)
1	99.9
2	99.9
3	99.9
4	99.9
5	99.9

Note: Plate count totals for each stage are available upon request.

Mean Positive Control Count: 2,082 plaque forming units (PFU)  
 Negative Monitor Count: <1 PFU  
 Mean Particle Size (MPS): 2.8  $\mu$ m

  
 Study Director

Sarah Smit, B.S.

*22 May 2014*  
 Study Completion Date