



our reference
YR0415_2020

date
25 February 2020

Certification report

1. Description of the tested article:

Reference: Bakewell, 99.3 % Polyester, 0.7 % Carbon Graft
100 washes @73°C and tumble dried
Description: Green fabric with black lines

2. Executed tests:

ISO 22610: 2006*
ISO 22612: 2005*
ISO 9073-10: 2003*
ISO 11737-1: 2018
ISO 811: 2018*
EN 13938-1: 1999— dry and wet*
EN 29073-3: 1992— dry and wet*

} According to EN 13795-1 (2019)

* tests assessed after steam sterilization 4 minutes at 134°C

Detailed results can be found in:

Analysis report Nr. 19.06906.01 dated 5 February 2020.

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The results of the analysis cover the received samples. Centexbel is not responsible for the representativeness of the samples.

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3. Conclusions:

Table 1: Surgical drapes - Determination of conformity against performance requirements

CHARACTERISTIC	UNIT	EN 13795-1 (2019) REQUIREMENTS			
		Standard performance		High performance	
		Critical product area	Less critical product area	Critical product area	Less critical product area
Microbial penetration - Dry	CFU	Not required	$Uq \leq 300$	Not required	$Uq \leq 300$
Microbial penetration – Wet	I_B	all results ≥ 2.8	Not required	all results = 6.0	Not required
Cleanliness - Microbial	CFU/100 cm ²	$Uq \leq 300$	$Uq \leq 300$	$Uq \leq 300$	$Uq \leq 300$
Particle release	log ₁₀ (lint count)	$Uq \leq 4.0$	$Uq \leq 4.0$	$Uq \leq 4.0$	$Uq \leq 4.0$
Resistance to liquid penetration	cm H ₂ O	$Lq \geq 30$	$Lq \geq 10$	$Lq \geq 100$	$Lq \geq 10$
Bursting strength – Dry	kPa	$Lq \geq 40$	$Lq \geq 40$	$Lq \geq 40$	$Lq \geq 40$
Bursting strength – Wet	kPa	$Lq \geq 40$	Not required	$Lq \geq 40$	Not required
Tensile strength - Dry	N	$Lq \geq 15$	$Lq \geq 15$	$Lq \geq 20$	$Lq \geq 20$
Tensile strength - Wet	N	$Lq \geq 15$	Not required	$Lq \geq 20$	Not required

(Uq = Upper quartile, Lq = Lower quartile)

Table 2 : Surgical gowns - Determination of conformity against performance requirements

CHARACTERISTIC	UNIT	EN 13795-1 (2019) REQUIREMENTS			
		Standard performance		High performance	
		Critical product area	Less critical product area	Critical product area	Less critical product area
Microbial penetration - Dry	CFU	Not required	$Uq \leq 300$	Not required	$Uq \leq 300$
Microbial penetration – Wet	I_B	all results ≥ 2.8	Not required	all results = 6.0	Not required
Cleanliness - Microbial	CFU/100 cm ²	$Uq \leq 300$	$Uq \leq 300$	$Uq \leq 300$	$Uq \leq 300$
Particle release	log ₁₀ (lint count)	$Uq \leq 4.0$	$Uq \leq 4.0$	$Uq \leq 4.0$	$Uq \leq 4.0$
Resistance to liquid penetration	cm H ₂ O	$Lq \geq 20$	$Lq \geq 10$	$Lq \geq 100$	$Lq \geq 10$
Bursting strength – Dry	kPa	$Lq \geq 40$	$Lq \geq 40$	$Lq \geq 40$	$Lq \geq 40$
Bursting strength – Wet	kPa	$Lq \geq 40$	Not required	$Lq \geq 40$	Not required
Tensile strength - Dry	N	$Lq \geq 20$	$Lq \geq 20$	$Lq \geq 20$	$Lq \geq 20$
Tensile strength - Wet	N	$Lq \geq 20$	Not required	$Lq \geq 20$	Not required

(Uq = Upper quartile, Lq = Lower quartile)



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Table 3: Test results

SAMPLE	CHARACTERISTIC	UNIT	RESULTS	
Bakewell,99.3 % Polyester, 0.7 % Carbon Graft 100 washes @73°C and tumble dried	Microbial penetration - Dry	CFU	Uq	18
	Microbial penetration – Wet	I_B	/	3.8 – 4.1 – 3.5 – 3.9 – 3.6
	Cleanliness - Microbial	CFU/100 cm ²	Uq	161
	Particle release (both sides)	log10 (lint count)	Uq	1.6 / 2.0
	Resistance to liquid penetration	cm H ₂ O	Lq	27.0
	Bursting strength – Dry (both sides)	kPa	Lq	859 / 914
	Bursting strength – Wet (both sides)	kPa	Lq	840 / 846
	Tensile strength – Dry (both directions)	N	Lq	> 800 / 514
	Tensile strength – Wet (both directions)	N	Lq	> 800 / 504

According to EN 13795-1 (2019), the fabric “**Bakewell,99.3 % Polyester, 0.7 % Carbon Graft - 100 washes @73°C and tumble dried**” fulfils the requirements to be used for :

- Gowns – Standard performance for Critical and Less Critical product areas
- Gowns – High performance for Less Critical product area
- Drapes – Standard performance for Less Critical product area
- Drapes – High performance for Less Critical product area

Certification report No. YR0415_2020 is valid until 05/02/2025.

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