

**Crown Name Disposable Hygiene Products
FTY Ltd
Ms. Cyndy Zhang
Changhang Building Room 1805 18/F No 69
Yanjiang Avenue
430021 WUHAN
China**

Your notice of	Your reference	our reference	date
		YR0822_2016	19 May 2017

Certification report

1. Description of the tested article:

Reference : Yellow SMMS 23gsm, non sterile
Description: Yellow non woven

2. Executed tests:

ISO 22610: 2006
ISO 22612 : 2005
ISO 9073-10 : 2003
EN ISO 11737-1 : 2006 + AC : 2009
EN 20811 : 1992
EN 13938-1 : 1999– dry and wet
EN 29073-3 : 1992– dry and wet

} According to EN 13795:2011+A1:2013

Detailed results can be found in:

Analysis reports Nr. 16.02988.02 dated 19 May 2017 and 17.02043.01 dated 19 May 2017.

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CENTEXBEL GENT
Technologiepark 7
BE-9052 Zwijnaarde (Gent)
Tel. +32 9 220 41 51
Fax +32 9 220 49 55
e-mail gent@centexbel.be



CENTEXBEL
Rue du Travail 5
BE-4460 Grâce-Hollogne
Tel. +32 4 296 82 00
Fax +32 4 296 82 99
e-mail g-h@centexbel.be

3. Conclusions:

Table 1: Performance requirements for surgical drapes

CHARACTERISTIC	UNIT	EN 13795 REQUIREMENTS			
		Standard performance		High performance	
		Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration - Dry	CFU	Not required	≤ 300	Not required	≤ 300
Resistance to microbial penetration – Wet	I_B	≥ 2.8	Not required	6.0	Not required
Cleanliness - Microbial	CFU/100 cm ²	≤ 300	≤ 300	≤ 300	≤ 300
Cleanliness – Particulate matter	IPM	≤ 3.5	≤ 3.5	≤ 3.5	≤ 3.5
Linting	Log ₍₁₀₎ (lint count)	≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0
Resistance to liquid penetration	cm H ₂ O	≥ 30	≥ 10	≥ 100	≥ 10
Bursting strength - dry	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength - wet	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength - dry	N	≥ 15	≥ 15	≥ 20	≥ 20
Tensile strength - wet	N	≥ 15	Not required	≥ 20	Not required

Table 2: Performance requirements for surgical gowns

CHARACTERISTIC	UNIT	EN 13795 REQUIREMENTS			
		Standard performance		High performance	
		Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration - Dry	CFU	Not required	≤ 300	Not required	≤ 300
Resistance to microbial penetration – Wet	I_B	≥ 2.8	Not required	6.0	Not required
Cleanliness - Microbial	CFU/100 cm ²	≤ 300	≤ 300	≤ 300	≤ 300
Cleanliness – Particulate matter	IPM	≤ 3.5	≤ 3.5	≤ 3.5	≤ 3.5
Linting	Log ₍₁₀₎ (lint count)	≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0
Resistance to liquid penetration	cm H ₂ O	≥ 20	≥ 10	≥ 100	≥ 10
Bursting strength - dry	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength - wet	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength - dry	N	≥ 20	≥ 20	≥ 20	≥ 20
Tensile strength - wet	N	≥ 20	Not required	≥ 20	Not required

Table 3: Results obtained on the tested sample

SAMPLE	CHARACTERISTIC	UNIT	RESULTS
Yellow SMMS 23gsm	Resistance to microbial penetration - Dry	CFU	1
	Resistance to microbial penetration – Wet	I_B	3.1
	Cleanliness - Microbial	CFU/100 cm ²	< 6
	Cleanliness – Particulate matter	IPM	1.3
	Linting	Log ₍₁₀₎ (lint count)	1.8
	Resistance to liquid penetration	cm H ₂ O	41.0*
	Bursting strength - dry	kPa	111
	Bursting strength - wet	kPa	99
	Tensile strength – dry	N (Machine direction/Cross direction)	69.0 / 26.3
	Tensile strength – wet	N (Machine direction/Cross direction)	66.6 / 24.0

* 1 value at 12.5 cm H₂O

According to EN 13795:2011+A1:2013, the non woven **Yellow SMMS 23gsm** fulfils the requirements to be used for drapes and gowns – Standard and high performance for Less Critical areas.

Certification report No. YR0822_2017 is valid until 11/07/2021

Stijn Devaere, Ph D

Director of Services