

Wednesday, 18 March 2020

**Subject: Manufacturer Statement Regarding EN 13795:2011+A1:2013 for Aero-Chrome Surgical Gowns**

Dear Valued Halyard Health Customer:

This is to certify that the following Surgical Gown codes meet the EN 13795 test requirements;

- Sterile versions: 44689, 44690,44691,44693,44694
- Non-sterile versions: 44662NS,44667NS,44668NS

**Aero Chrome and Aero Chrome Specialty Surgical Gowns - Five Years Accelerated Aging**

Test Item	Standard	Unit	Requirement		*3 Lot - Average Result **EN ISO 11737-1 Tested at Time Zero only	
			High Performance		High Performance	
			Critical Area	Less critical area	Critical Area	Less critical area
Resistance to Microbial Penetration - Wet	ISO 22610:2006	IB	6	Not required	6 IB	Not required
Resistance to Microbial Penetration - Dry	ISO 22612:2005	CFU	Not required	≤ 300	Not required	≤ 1 CFU
Cleanliness-microbial	EN ISO 11737-1 (2006+AC:2009)	CFU/100 cm <sup>2</sup>	≤ 300	≤ 300	**97.2 CFU/100 cm <sup>2</sup>	**99.4 CFU/100 cm <sup>2</sup>
Resistance to liquid penetration	EN 20811:1992	cm H <sub>2</sub> O	≥ 100	≥ 10	> 204 cm H <sub>2</sub> O	55.7 cm H <sub>2</sub> O
Linting, 3 μ results from Nelson Labs are ≥ 1 μ (worse case)	ISO 9073-10	log 10 (lint count)	≤ 4.0	≤ 4.0	1.97	1.64
Cleanliness-Particulate Matter (IPM)	ISO 9073-10	IPM	≤ 3.5	≤ 3.5	1.78 IPM	1.35 IPM
Bursting Strength - Dry	EN 13938-1:1998	kPa	≥ 40	≥ 40	241 kPa	125 kPa
Bursting Strength - Wet	EN 13938-1:1998	kPa	≥ 40	Not required	258 kPa	Not required
Tensile Strength - Dry	EN 29073-3:1992	N	≥ 20	≥ 20	MD =89.8 N CD = 44.9 N	MD =55.1 N CD =30.3 N
Tensile Strength - Wet	EN 29073-3:1992	N	≥ 20	Not required	MD =94 N CD = 47 N	Not required

\*EN 13795 testing was conducted at Nelson Labs in Report 1133710-S09-S09 dated December 18, 2018 for five years accelerated. \*\*EN 13795 testing was conducted at Nelson Labs in Report 1052415-S10 dated June 11, 2018 for Time Zero testing.

*Nelson Labs is an ISO 17025 certified lab in Salt Lake City, Utah USA. Address for the test location is: 6280 S. Redwood Road, Salt Lake City, Utah 84123.*

Laser Ignition Test was conducted at Centexbel in Report 18.03135.01 dated May 30, 2018. Test results = I1\_95 best class for Critical and Non-critical areas.

*Centexbel is an ISO 17025 certified lab in Belgium Europe, address for test location is: Rue du Travail 54460, Grâce-Hollogne, Belgium.*

If you have any questions or concerns, please contact your local Halyard Account Manager or your Customer Service Agent.

Thank you for being a valued Halyard customer, we appreciate your continued support.  
Best regards

Bruno Pozzoli  
Marketing Manager  
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