

## General Tensile Testing Final Report

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Test Article: ZSTS001  
Purchase Order: ZSTS001  
Study Number: 999127-S01  
Study Received Date: 27 Oct 2017  
Testing Facility: Nelson Laboratories, LLC, a Business Unit of Sterigenics International  
6280 S. Redwood Rd.  
Salt Lake City, UT 84123 U.S.A.  
Test Procedure(s): Standard Test Protocol (STP) Number: STP0066 Rev 09  
Deviation(s): None

**Summary:** This procedure is designed to determine the tensile strength. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Appendix A Number of Pages: 2

**Results:** The results are summarized in Appendix A.

**Test Method Acceptance Criteria:** No test method acceptance criteria currently exist for this test.

**Procedure:** Prior to testing, the test articles were conditioned for a minimum of 8 hours at  $21 \pm 2^\circ\text{C}$  and  $65 \pm 5\%$  relative humidity.

The fabric to be tested was cut into specimens approximately 50 mm wide and 150 mm long. When possible, specimens were cut in both the machine direction and the cross direction of the fabric examined. These specimens were tested on an Instron<sup>®</sup> physical testing instrument. The crosshead speed of the instrument was set to 100.0 mm per minute, and the distance between the grips was set to 100 mm. Each fabric specimen was placed into the pneumatic grips of the Instron<sup>®</sup> and centered. The tensile test was initiated and repeated for all specimens.



  
Study Director

Jennifer Gygi, B.S., SM/RM(NRCM)

  
Study Completion Date



999127-S01

# Appendix A



Sponsor	Wuhan Zonsen Medical Products Co., Ltd.
Lab number	999127
User	Simon Day
Test Article	ZSTS001
Testing temperature	24 °C
Testing humidity	45 %RH
Crosshead speed	100.0 mm/min
Grip distance	100 mm
Size	50 x 150 mm - hand cut
Jaw faces	1 x 3 inch rubber coated
Fabric type	Nonwoven
Fabric direction	Ear to Ear
Testing condition	Conditioned (dry)
Equipment	Instron 3343 with Bluehill 3 software
Instron Equipment ID	3166

Instron file designation: 999127.is\_tens  
ISO 9073 - Tensile of fabrics

### Results

	Breaking Strength [N]	Elongation (%)
1	104.2	69.8
2	105.5	74.8
3	99.7	62.8
4	101.0	70.5
5	104.3	66.7
Mean	102.9	68.9
Standard deviation	2.47	4.48

Notes  
NA



Sponsor	Wuhan Zonsen Medical Products Co., Ltd.
Lab number	999127
User	Simon Day
Test Article	ZSTS001
Testing temperature	24 °C
Testing humidity	48 %RH
Crosshead speed	100.0 mm/min
Grip distance	100 mm
Size	50 x 150 mm - hand cut
Jaw faces	1 x 3 inch rubber coated
Fabric type	Nonwoven
Fabric direction	Nose to Chin
Testing condition	Conditioned (dry)
Equipment	Instron 3343 with Bluehill 3 software
Instron Equipment ID	3166

Instron file designation: 999127\_1.is\_tens  
ISO 9073 - Tensile of fabrics

### Results

	Breaking Strength [N]	Elongation (%)
1	69.4	71.3
2	58.9	52.5
3	65.3	69.2
4	64.8	62.3
5	60.0	51.7
Mean	63.7	61.4
Standard deviation	4.28	9.14

### Notes

NA