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A Sotera Health company

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ISO 16603 Synthetic Blood Penetration Final Report

Test Article:	Product Name:Disposable Medical Protective Gown Model:ZKF-01 Lot No:2020080503
Purchase Order:	QHT20080426
Study Number:	1340490-S01
Study Received Date:	11 Sep 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Protocol Number: 202005257 Rev 01
Deviation(s):	None

Summary: This test method was performed to evaluate the resistance of protective materials to penetration by synthetic blood under conditions of continuous liquid contact. Protective materials' pass/fail determinations are based on visual detection of synthetic blood penetration. Test articles were conditioned for a minimum of 24 hours at 21 ± 5°C and 60 ± 10% relative humidity (RH), and then tested for liquid penetration using synthetic blood. The synthetic blood penetration method complies with ISO 16603:2004; test articles thickness and weight measurements were not performed, sampling was at the discretion of the sponsor. The synthetic blood used for testing complies with the ASTM F1670 standard. 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.

Number of Test Articles Tested:	3
Test Article Side Tested:	Outside
Test Article Preparation:	~75 X 75 mm squares, aseptically cut from the critical chest material at random
Test Article Sealed:	Paraffin Wax
Exposure Procedure:	C (no retaining screen)
Highest Pressure with No Visible Penetration:	20 kPa (Test Article 1) 14 kPa (Test Article 2) 14 kPa (Test Article 3)

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Jennifer Jorgenson electronically approved	20 Oct 2020 00:11 (+00:00)
Study Director Jennifer Jorgenson	Study Completion Date and Time

Results:

Test Article Number	Pressure (kPa)	Synthetic Blood Penetration	Result
1	0, 1.75, 3.5, 7, 14, 20	None Seen	Pass
2	0	None Seen	Pass
	1.75	None Seen	Pass
	3.5	None Seen	Pass
	7	None Seen	Pass
	14	None Seen	Pass
	20	Yes	Fail
3	0	None Seen	Pass
	1.75	None Seen	Pass
	3.5	None Seen	Pass
	7	None Seen	Pass
	14	None Seen	Pass
	20	Yes	Fail
Negative Control	0, 1.75, 3.5, 7, 14, 20	None Seen	Acceptable
Positive Control	0, 1.75, 3.5	Yes	Acceptable

Acceptance Criteria: The positive control must be positive for synthetic blood penetration. The negative control must be negative for synthetic blood penetration.

Procedure: The test articles were loaded into the test cell and the bolts were torqued to 13.6 Newton meters (Nm) (120 inch pounds) in a criss-cross technique. Test articles were challenged with approximately 56-62 mL of synthetic blood and pressurized according to ISO 16603 Procedure C, or until failure. At the conclusion of the test, the test articles were observed for synthetic blood penetration. The synthetic blood was prepared according to ASTM F1670 at a surface tension of 40 ± 5 dyn/cm. The results were scored as pass or fail based on synthetic blood penetration observations.

Table 1. ISO 16603 Specimen Exposure Procedures:

Procedure	Pressure/Time Sequence
C	0 kPa for 5 minutes, followed by 1.75 kPa for 5 minutes, followed by 3.5 kPa for 5 minutes, followed by 7 kPa for 5 minutes, followed by 14 kPa for 5 minutes, followed by 20 kPa for 5 minutes