SURGICAL MATERIAL TESTING LABORATORY

TEST REPORT

Examination Glove Report

Report No: 18/5747/1

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1 Name & Address of Client/Requesting Authority

2 Introduction

This document presents the results of Nitrile Examination Gloves tested to BS EN 455 Parts 1[1], 2[2] and 3 Total Extractable Protein[3] and Residual Powder[4].

3 Test Products/Samples for this project

Table 1: Samples

Supplier	Product Name	Description	Catalogue Number	Batch/Lot Number	Quantity	Date received	SMTL Sample ID
1	Nitrile Examination Gloves	Examination Gloves. Powder-free. Size Medium. Manufacture date March 2018	1	1 1	400	16/07/2018	1

NOTE: The test results in this report relate only to the test sample(s) analysed.

3.1 Departures/Abnormalities of Sample Condition

None.

4 Date of Testing

19th July - 1st August 2018

5 Testing Details

5.1 Perforations - TM-22[5]

The number and location of perforations in a designated sample size was noted in accordance with *BS EN 455-1:2000 Medical gloves for single use. Requirements and testing for freedom from holes* using the SMTL test method TM-22.

Each glove batch was sampled in accordance with *ISO 2859-1* general inspection level 1, utilising a minimum sample size and corresponding acceptance/rejection numbers equivalent to sample size code letter L and an acceptance quality level (AQL) of 1.5

Gloves were selected at random and attached to the base of a plastic tube of diameter 68mm. Cuffs were located at a point 3.8cm from the base of the tube and secured onto the tube.

Gloves were then filled with 1000 ± 50ml of water at a temperature of (15-35°C) and examined for evidence of leaks. Gloves were allowed to hang for 2-3 minutes, then again examined for evidence of leaks. The position and nature of any leaks was recorded. Any leaks identified within 40mm of the cuff were disregarded.

5.2 Force at break - TM-342[6]

The force at break of the gloves was measured in accordance with *BS EN 455-2:2015 Medical gloves for single use. Requirements and testing for physical properties* using SMTL test method TM-342.

The strength of the gloves was determined during shelf life and following ageing (7 days at 70 ± 2°C). Dumb-bell test pieces were cut from 13 individual (or from seven pairs) gloves from the same lot, following a conditioning period of at least 16hrs. Using a tensometer with a cross-head speed of 500mm/min the force at break in newtons (N) was recorded.

The single wall thickness of each dumb-bell and the double wall thickness of the middle finger tip of each glove was measured using a thickness gauge and a correction factor applied if applicable.

The median of the 13 samples (with correction factor applied if necessary) was calculated.

5.3 Dimensions - TM-343[7]

The length and width of the gloves was measured in accordance with *BS EN 455-2:2015 Medical gloves for single use. Requirements and testing for physical properties* using SMTL test method TM-343.

Length

The glove length was measured by freely suspending the glove by the middle finger on a vertical graduated rule with a rounded tip. Folds and wrinkles were removed without stretching the glove and the minimum length recorded.

This was repeated so that a total of 13 gloves were measured and the median length was calculated.

Width

The width of the glove was measured using a calibrated rule to the nearest mm, when the glove was placed onto a flat surface.

This was repeated so that a total of 13 gloves were measured and the median width was calculated.

5.4 Extractable protein - TM-230[8]

The measurement of total extractable protein of the gloves was determined in accordance with Annex A of *BS EN 455-3:2015 Medical gloves for single use. Requirements and testing for biological evaluation* using TM-230.

A quantitative test method, based upon a Modified Lowry Assay, was used, which comprised three main parts. In the first part, residual soluble protein was aqueously extracted from a known weight of glove test sample using TES buffer as the extractant. The extraction procedure employed was such that both the inside and outside surfaces of the material were extracted simultaneously. Following this, the extracted protein was purified by a process which precipitates the proteins and removes interfering, water-soluble substances. In the final part, the optical density of a sample of the test extract was determined using a microplate plate reader at a wavelength of 650nm. A series of ovalbumin protein standard solutions were also prepared using extraction buffer as a diluent. The protein in each standard solution was precipitated and assayed in the same way as for the glove test samples. The optical density value of each well was recorded by an automated computer program linked to the microplate reader which performs regression analysis on the standard curve and calculates the protein concentration in µg per ml in each of the unknown glove extract samples. The total amount of protein extracted per glove was then calculated from which the total extractable protein in µg per gram of glove was determined.

Extraction buffer was used as a blank.

Four glove extracts were tested for each product.

The mean protein content of the four determinations was calculated and reported.

5.5 Removable Surface Powder - TM-391[9]

The measurement of readily removable powder on the surface of gloves for medical use was determined in accordance with *BS EN ISO 21171 : 2006* using TM-391.

The surfaces of 5 gloves are washed with water to remove the water-insoluble powder, the extract is filtered, and the filter dried then weighed. The weight of removed powder is then determined as the difference between the initial and final weight of the filter.

5.6 Standards relevant to the test method

- Perforation testing (TM-22) is performed in accordance with BS EN 455 Part 1: 2000[1]
- Force at break (TM-342) and dimension (TM-343) testing requirements are performed in accordance with BS EN 455 Part 2: 2015[2]
- Total extractable protein testing (TM-230) is in accordance with annex A of BS EN 455 Part 3: 2015[3]
- Determination of removable surface powder (TM-391) is performed in accordance with BS EN ISO 21171:2006[4]
- The limits of the test are read in conjunction with BS EN 455 Part 3: 2015[3][5]

5.7 Testing conditions

Force At Break

- Testing and conditioning was performed at 23 ±2°C, and at a relative humidity of 50 ±10%.

Total Extractable Protein

- The extraction was performed at 25 ±5°C with shaking for 120 ±5 minutes. The precipitation and concentration of protein was performed at 25 ±5°C.

Removeable Surface Powder

- The testing was performed at 25 ±5°C. The drying was performed at 100 ±5°C.

5.8 Deviations/exclusions from, and additions to standard methods

Force At Break

- The test pieces were conditioned and tested at a relative humidity of 50 ± 10% instead of 50 ± 5%.

Removeable Surface Powder

- The temperature was not monitored to confirm within 25 ±5°C during the testing, performed at ambient room conditions.

5.9 Uncertainty of Measurement

Uncertainty of measurement (UoM) has not been taken into account when interpreting the test results compliance with limits. However, the UoM budget for the relevant quantitative test methods are presented in Appendix A, and can be used to assess compliance of individual test results taking into account the UoM.

5.10 Sampling Details

All samples were selected and supplied by the client.

The batch size of the gloves supplied was not stated by the client. In accordance with BS EN 455 Part 1, a batch size between 35,001 to 150,000 was chosen, and therefore 50 gloves per stage were tested for perforations using General Inspection Level I at an AQL of 1.5%. With reference to Table 3, the sample size was tested up to the fifth sampling stage or until compliance or non compliance was determined.

5.11 Sample Preparation

Samples were prepared according to the relevant test method used.

6 Results

6.1 Perforation Testing

The results of perforation testing are presented in Table 2. Compliance has been determined with reference to Table 3.

Table 2: Perforation Testing results for Sample 68961

Stage No	Cumulative No Tested	Cumulative No Failed	Compliance
First	50	0	Complies
Second	100	-	
Third	150	-	
Fourth	200	-	
Fifth	250	-	

Table 3: Multiple sampling - Perforation compliance (BS EN 455-1)

	Cumulative No Gloves Tested	Accept	Reject
First stage	50	0	4
Second stage	100	1	6
Third stage	150	3	8
Fourth stage	200	5	9
Fifth stage	250	9	10

6.2 Force at Break

The results of testing are presented in Table 4. Compliance has been determined with reference to Table 5.

Table 4: Force at Break results for Sample 56961

Sample	Force at Break (N) Unchallenged	Force at Break (N) Challenged
1	7.0	6.6
2	6.2	7.2
3	6.8	6.6
4	7.0	7.5
5	7.4	7.4
6	7.2	7.3
7	7.5	6.6
8	7.0	8.0
9	7.5	7.2
10	7.1	6.4
11	7.0	7.3
12	8.0	6.4
13	8.0	5.6
Median Result	7.1 **Complies**	7.2 **Complies**

Table 5: Median Force at Break Limits (BS EN 455-2)

	Limit
Force at break during shelf life (Unchallenged)	≥ 6.0N
Force at break after challenge testing (Within 12 months of manufacture)	≥ 6.0N

6.3 Dimensions

The results of dimension testing are presented in Table 6. Compliance has been determined with reference to Table 7.

Table 6: Dimension Testing results for Sample 56961

Sample	Length (mm)	Width (mm)
1	239	97
2	244	97
3	243	99
4	241	99
5	239	98
6	237	99
7	239	96
8	242	98
9	240	98
10	239	98
11	241	99
12	242	99
13	240	99
Median Result	240 **Complies**	98 **Complies**

Table 7: Dimension Limits (BS EN 455-2)

	Median Length	Median Width
Medium	≥ 240mm	95 ± 10mm

6.4 Total Extractable Protein

The total amount of extractable protein per gram for each of the inner and outer surface test samples is presented in Table 8.

Table 8: Total Extractable Protein results for Sample 56961

Sample	Total Extractable Protein (µg/g) †
1	< 12.2
2	< 11.8
3	< 12.2
4	< 12.6
Mean	Cannot be calculated

† Ovalbumin Equivalent Protein

(Mean value not calculated as the measured concentration of protein in one or more of the samples was below the calculated concentration of the lowest standard in this test.)

6.5 Removable Surface Powder

The total amount of residual surface powder per glove is presented in Table 9.

Table 9: Removable Surface Powder results for Sample 56961

Mass (mg/glove)	Compliance †
0.6	Complies

† For compliance with BS EN 455 Part 3: 2015[10] powder-free gloves should contain no more than 2mg powder per glove.

7 Authorisation

Approved and signed electronically. Please see last page of this document.

Pete Phillips, Director, SMTL.

Appendix A

A.1 Medical Gloves - EN 455 Uncertainty of Measurement

A.1.1 TM-342 EN 455-2 Force at Break

UoM for TM-342 Force at Break of Medical Glove testing is 1.6%. The reported uncertainty is an expanded uncertainty using a coverage factor of k=2, which provides a level of confidence of approximately 95%.

A.1.2 TM-343 EN 455-2 Dimensions

UoM for TM-343 Dimensions of Medical Glove testing is 1.1mm for length and 1.5mm for width measurements. The reported uncertainty is an expanded uncertainty using a coverage factor of k=2, which provides a level of confidence of approximately 95%.

A.1.3 TM-391 EN 455-3 Powder

The UoM for TM-391 glove powder testing is 0.2mg. The reported uncertainty is an expanded uncertainty using a coverage factor of k=2, which provides a level of confidence of approximately 95%.

A.1.4 TM-254 EN 455-3 Endotoxin

The UoM for TM-254 endotoxin testing is 23%. The reported uncertainty is an expanded uncertainty using a coverage factor of k=2 which provides a level of confidence of approximately 95%.

References

(1) *Medical gloves for single use - part 1: Requirements and testing for freedom from holes. BS EN 455-1:2000.*

(2) *Medical gloves for single use - part 2: Requirements and testing for physical properties. BS EN 455-2:2015.*

(3) *Medical glove for single use - part 3: Requirements and testing for biological evaluation. annex A:Method for the determination of aqueous extractable proteins in natural rubber gloves using the modified lowry assay. BS EN 455-3:2015.*

(4) *Medical gloves - determination of removable surface powder. BS EN ISO 21171 2006.*

(5) SMTL. *Detection of perforations in medical gloves to BS EN 455 Part 1.* (TM-22).

(6) SMTL. *Force at break testing of medical gloves to BS EN 455 Part 2.* (TM-342).

(7) SMTL. *Determination of dimensions of medical gloves to BS EN 455 Part 2.* (TM-343).

(8) SMTL. *Determination of extractable protein in natural rubber gloves.* (TM-230).

(9) SMTL. *Medical Gloves - Determination of Removable Surface Powder.* (TM-391).

(10) *Medical glove for single use - part 3: Requirements and testing for biological evaluation. BS EN 455-3:2015.*

Digitally signed by:
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