Surgical Material Testing Laboratory

Test Report

EN 455 Medical Glove Testing

Report No: 16/5200/1

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22nd July 2016

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2 Introduction

This document presents the results of Gompels Latex Medical Grade Gloves tested to BS EN 455 Parts 1[(1)] and 2[(2)].

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
Gompels Healthcare	Gompels Latex	Powder Free Medical Grade Gloves, Large, Non-sterile	78342	31315305	400	06/07/2016	49740

3.1 Departures/Abnormalities of Sample Condition

None.

4 Date of Testing

6th - 22nd July 2016

5 Testing Details

5.1 Perforations - TM-22[3]

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[4]

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[5]

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 gloves 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.

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.

5.4 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 are performed in accordance with *BS EN 455 Part 2: 2015*[(2)]

5.5 Testing conditions

Force At Break

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

5.6 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%.

5.7 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.

5.8 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 49740

Stage No	Cumulative No Tested	Cumulative No Failed	Compliance
First	50	1	Continued to next stage
Second	100	-	**Complies**
Third	150	-	
Fourth	200	-	
Fifth	250	-	

- Perforations were defected in the finger (1 glove).

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 49740

Sample	**Force at Break (N) Unchallenged**	**Force at Break (N) Challenged**
1	7.2	6.5
2	7.9	7.2
3	8.3	7.3
4	8.3	7.0
5	7.0	6.7
6	6.7	6.7
7	6.3	7.6
8	6.8	7.8
9	7.5	6.4
10	8.3	8.4
11	8.1	7.2
12	7.4	7.6
13	8.0	8.0
Median Result	7.5 **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 49740

Sample	Length (mm)	Width (mm)
1	249	102
2	250	104
3	251	105
4	250	107
5	245	104
6	249	105
7	255	108
8	249	103
9	257	105
10	257	106
11	244	106
12	255	107
13	250	104
Median	250	105
Result	**Complies**	**Complies**

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

	Median Length	Median Width
Large	≥ 240mm	110 ±10mm

7 Authorisation

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

Pete Phillips, Director, SMTL.

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

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

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

This document is signed by

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	Date/Time	Tue Aug 23 15:17:59 BST 2016
	Issuer-Certificate	CN=Certum Level III CA, OU=Certum Certification Authority, O=Unizeto Technologies S.A., C=PL
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Note	This document has been digitally signed by Pete Phillips, Director SMTL. You can verify this signature with Adobe Acrobat.	