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subject: **EN 455 Medical Glove Testing**

S . M . T . L .

date: **19th February 2015**

from: **Victoria Baines
Princess of Wales
Tel: +44-1656-752820**

Report No: 15/4599/1

Test Report

15/4599/1

1. Name & Address of Client/Requesting Authority.

Gompels HealthCare Ltd
No.1 Swift Way
Bowerhill Ind Est
Melksham
Wiltshire
SN12 6GX

Email: lindsay@gompels.co.uk

2. Introduction

This document presents the results of Gompels Healthcare Proform Vinyl Powder Free Examination Gloves tested to BS EN 455 Parts 1⁽¹⁾, 2⁽²⁾ and Part 3 Residual Powder.⁽³⁾

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3. Test Product(s)/Sample(s)

TABLE 1. Test Product(s)/Sample(s) tested by SMTL.

Manufacturer/ Supplier	Item	Cat No	Batch/Lot No	Date of Manufacture	Quantity	Date Received	SMTL Sample I.D.
Gompels Healthcare	Proform Vinyl Powder-Free Examination Gloves	70642	17529	06/2014	500	04/02/2015	45276

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

4th February - 12th February 2015

5. Testing Details

5.1 Perforations

The number and location of perforations in a designated sample size was noted using SMTL test method TM-22.⁽⁴⁾

5.2 Force at break

The force at break before and after challenge testing (aged at 70°C for 7 days) of medical gloves was measured using SMTL test method TM-342.⁽⁵⁾

5.3 Dimensions

The dimensions of the gloves were determined using SMTL test method TM-343.⁽⁶⁾

5.4 Removable Surface Powder

The measurement of removable surface powder was determined using SMTL test method TM-391.⁽⁷⁾

5.5 List of SMTL Test Methods Used.

- TM-22 - Detection of perforations in medical gloves to BS EN 455 Part 1⁽⁴⁾
- TM-342 - Force at break testing of medical gloves to BS EN 455 Part 2⁽⁵⁾
- TM-343 - Determination of dimensions of medical gloves to BS EN 455 Part 2⁽⁶⁾
- TM-391 - Determination of removable surface powder to BS EN 455 Part 3⁽⁷⁾

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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 are performed in accordance with BS EN 455 Part 2: 2009 +A2:2013⁽²⁾
- Determination of removable surface powder (TM-391) is performed in accordance with BS EN ISO 21171:2006.⁽⁸⁾

The limits of the test are read in conjunction with BS EN 455 Part 3: 2006.⁽³⁾

5.7 Deviations/exclusions from, and additions to standard methods.

- The test pieces were conditioned at a relative humidity of 50±20% not 50±5% as in the standard.

5.8 Sampling Details

All samples were selected and supplied by the client.

The batch size of the gloves supplied was stated to be by the client. In accordance with BS EN 455 Part 1, a batch size between 0 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⁽⁹⁾, the sample size was tested up to the fifth sampling stage or until compliance or non compliance was determined.

5.9 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. Results of Perforation Testing

Glove	Stage No	Cumulative No Tested	Cumulative No Failed	Complies /Does Not Comply
Proform Vinyl	First	50	0	COMPLIES
	Second	-	-	
	Third	-	-	
	Fourth	-	-	
	Fifth	-	-	

TABLE 3. BS EN 455 Part 1 Perforation Compliance - Multiple sampling

	Cumulative No Gloves Tested	Batch size 0 - 150,000	
		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

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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

Glove	Sample	Force At Break (N)		Complies/ Does Not Comply
		Unchallenged	Challenged	
Proform Vinyl	1	3.2*	3.5*	COMPLIES
	2	4.2*	4.8	
	3	3.7*	4.5	
	4	3.7*	4.6	
	5	3.9*	4.4	
	6	3.2*	3.9*	
	7	3.3	4.4	
	8	4.6	4.6	
	9	4.2*	4.2	
	10	3.5*	4.3	
	11	4.3	3.5*	
	12	4.3	3.9*	
	13	4.0	4.9	
	Mean	3.9	4.4	

Note:

* Indicates that a correction factor has been applied due to a difference in thickness of greater than 10% between the fingertip and the point from which the test piece has been taken (as described in Section 5.2.4 of BS EN 455-2:2009 +A2:2013).⁽²⁾

TABLE 5. BS EN 455 Part 2: 2009 +A2:2013 Compliance Median Force at Break Limits

	Examination/Procedure Gloves
	Thermoplastic Materials
Force at break During shelf life (Unchallenged)	≥3.6N
Force at break After challenge testing (Within 12 months of manufacture)	≥3.6N

Note:

- Gloves made from thermoplastic materials e.g. polyvinylchloride (PVC), polyethylene.

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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 Results

Glove	Size	Sample No	Length (mm)	Width (mm)	Complies/ Does Not Comply
Proform Vinyl	Medium	1	243	97	COMPLIES
		2	243	96	
		3	241	97	
		4	248	97	
		5	242	98	
		6	245	95	
		7	239	95	
		8	249	96	
		9	238	96	
		10	239	97	
		11	242	94	
		12	246	97	
		13	252	95	
		Median	243	96	

TABLE 7. BS EN 455 Part 2 - Dimension Compliance Limits

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

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6.4 Removable Surface Powder

The total amount of residual surface powder per glove is presented in Table 8.

TABLE 8. Removable Surface Powder Results

Glove	Mass (mg/glove)	Complies/ Does Not Comply †
Gompels Proform Vinyl Powder Free	0.56	COMPLIES

Note:

† For compliance with BS EN 455 Part 3: 2006⁽³⁾ powder-free gloves should contain less than 2mg powder per glove.

APPROVED:



Peter Phillips, Director, SMTL.

Date

23/2/12

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