Surgical Material Testing Laboratory

Test Report

Glove Report

Report No: 20/6155/1

Report Date: Monday 15th June, 2020

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Revision Information:
Template Version: 3c04a4e
Revision: 1.6
Revision date: Monday 15th June, 2020
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1 Name & Address of Client/Requesting Authority

Alf Walker
CLANDEBOYE AGENCIES LTD
Unit 30 Rathenraw Ind. Estate
Greystone Road
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2 Introduction

This document presents the results of Palm Care, Nitrile, Examination Gloves tested to BS EN 455 Part 3 Residual Powder[1].

3 Test Products/Samples for this project

Table 1: Samples

Manufacturer	Product Name	Description	Catalogue Number	Batch/Lot Number	Quantity	Date received	SMTL Sample ID
Hi Care Thai Gloves Co Ltd	Palm Care	Nitrile Examination Gloves, Powder Free, Size Medium, manufacturing date 6/2020	LB 35	06202007	100	11/06/2020	63645

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

The Manufacturer, Product Name, Description, Catalogue & Batch Numbers were provided by the client.

3.1 Departures/Abnormalities of Sample Condition

None.

4 Date of Testing

11th June 2020.

5 Location of Testing

All testing was performed at SMTL premises.

6 Testing Details

6.1 Removable Surface Powder - TM-391[2]

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

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

6.2 Standards relevant to the test method

- Determination of removable surface powder (TM-391) was performed in accordance with BS EN ISO 21171:2006[3]. The limits of the test are read in conjunction with BS EN 455 Part 3: 2015[1]

6.3 Testing conditions

6.3.1 Removeable Surface Powder - TM-391[2]

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

6.4 Deviations/exclusions from, and additions to standard methods

6.4.1 Removeable Surface Powder - TM-391[2]

- None.

6.5 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.

6.6 Sampling Details

All samples were selected and supplied by the client.

6.7 Sample Preparation

Samples were prepared according to the relevant test method used.

7 Results

7.1 Removable Surface Powder

The total amount of residual surface powder per glove is presented in Table 2.

Table 2: Removable Surface Powder results for Sample 63645

Mass (mg/glove)	**Compliance** †
1.4	**Complies**

† For compliance with BS EN 455 Part 3: 2015[1] powder-free gloves should contain no more than 2mg powder per glove.

8 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-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%.

References

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

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

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

Digitally signed by:
Pete Phillips, Director SMTL
2020.06.15 16:20:58 BST
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