



TOP GLOVE SDN. BHD.
The World's Largest Manufacturer of Gloves
GOOD HEALTH, SAFETY FIRST & BE HONEST

Registration No.
199101010171 (220483-T)
SST ID: B16-1808-22000008

A member of Top Glove Corporation Bhd, a Public Listed Company on Bursa Malaysia & Singapore Exchange.

FACTORY 9 : Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E., Malaysia.
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BUSINESS DIRECTIVE : To Produce Consistently High Quality Gloves At Efficient Low Cost.
FACILITIES : 47 Factories (Malaysia, Thailand, Vietnam & China), 750 Production Lines, 90 Billion Gloves Per Annum, 21,000 Employees.
MARKET : Exports to 195 countries worldwide with Marketing Offices in the USA, Germany and Brazil.

EU DECLARATION OF CONFORMITY (EU DoC)

Manufacturing Site : TOP GLOVE SDN. BHD
: Lot 4969, Jalan Teratai, Batu 6,
Off Jalan Meru, 41050 Klang,
Selangor D.E., Malaysia.

Single Registration Number (SRN) : MY-MF-000009690

European Authorized Representative : Top Glove Europe GmbH
Bliersheimer Str. 80A,
47229 Duisburg
Germany
Tel.: +49-(0)2065-76421-0,
Fax: +49-(0)2065-76421-19

Single Registration Number (SRN) : DE-AR-000004968

Name of Device : Latex Examination Gloves (ENW58)
Type : Powder Free
Classification : Class I, Non Sterile
Brand Name : PROSENSO™ (EWLTX58M)
Size : XS, S, M, L, XL
Conformity Assessment Procedure : Annex I, Annex II and Annex IV (Self-declared)
Rule : Rule 5
Intended use : The gloves are intended to be worn on the
hand of healthcare personnel during medical
examination procedures to protect cross-
contamination between healthcare personnel
and patient

We herewith declare with our own responsibility that above-mentioned product(s) with CE mark is fully compliance with General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentations are retained under the premise of manufacturer.

**“TO PREVENT CORRUPTION & BRIBERY. CORRUPTION & BRIBERY IS A CRIME.
BE HONEST AND NO CHEATING”**

DP 03/11/20/TGT

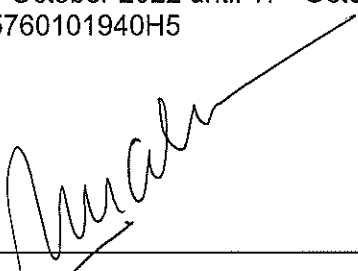
Applicable Standards:

No.	Standard	Descriptions	Date Published
1.	EN 455-1:2020	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	May 2020
2.	EN 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	April 2015
3.	EN 455-3:2015	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation.	April 2015
4.	EN 455-4:2009	Medical gloves for single use. Part 4: Requirements and testing for shelf life determination.	October 2009
5.	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	April 2021
6.	EN 62366-1:2015+A1:2020	Medical Devices – Part 1: Application of usability engineering to medical devices	August 2020
7.	EN ISO 14971:2019+A11:2021	Medical device - Application of risk management to medical device.	December 2021
8.	ISO 2859-1:2011	Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	June 2011
9.	EN ISO 10993-1:2020	Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process	Dec 2020
10.	ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	June 2009
11.	EN ISO 10993-10:2013	Biological evaluation of medical devices - Tests for irritation and skin sensitization.	August 2013
12.	EN ISO 10993-11:2018	Biological evaluation of medical devices. Tests for systemic toxicity	May 2018
13.	ISO 10993-12:2021	Biological evaluation for medical devices - Sample preparation and reference materials	January 2021
14.	ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation	January 2021
15.	ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied : General requirements.	July 2021
16.	MDR 2017/745 (Annex I: Chapter 2)	Requirements Regarding Design and Manufacture	April 2017
17.	MDR 2017/745 (Chapter I: Article 2)	Scope and Definitions	April 2017
18.	MDR 2017/745 (Annex VIII)	Classification rules	April 2017

No.	Standard	Descriptions	Date Published
19.	MDR 2017/745 (Annex II)	Technical Documentation	April 2017
20.	MDR 2017/745 (Chapter II: Article 11&12)	Guideline for Authorized Representative	April 2017
21.	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017
22.	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
23.	MEDDEV 2.12-1 rev 8	Medical Device Vigilance System	January 2013
24.	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013
25.	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance	April 2017
26.	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017
27.	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012
28.	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)	April 2017
29.	ISO/TR 20416	Medical devices — Post-market surveillance for manufacturers	July 2020
30.	MEDDEV 2.12/Rec 1	2.12 Post - Marketing Surveillance (PMS) post market / production	Revision 11, February 2000
31.	MDR 2017/745	Medical Device Regulation	April 2017

EU DoC Validity Date
Basic UDI – DI

: 18th October 2022 until 17th October 2023
: 955760101940H5


Name: Pn Noor Akilah Saidin
Designation: RA General Manager

Test Report No. : CRSSA/201150718-CA36668
Company : Top Glove Sdn Bhd
Lot 4969, Jalan Teratai, 6th Miles,
Off Jalan Meru, 41050 Klang, Selangor.

TEST REPORT

Sample Description : Latex Examination Polymer Powder Free Glove
Other Detail : RA/031/02/2020/D1
Size : Medium
Quantity Tested : 200 pieces
Test Conducted : Freedom from holes
Test Method : EN455 Part 1:2000
Testing Period : 02 Apr 2020 – 15 Apr 2020

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5 Accept : 7 Found : 1

Result : Within AQL

Remark : This remark supersedes report no. CRSSA/200437093-CA36668

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SGS (MALAYSIA) SDN BHD



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CHEE TUCK CHOON
SECTION HEAD
IKM No. M/3983/6401/12/14

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Test Report No. : CRSSA/201150715-CA52028
Company : Top Glove Sdn Bhd
Lot 4969, Jalan Teratai, 6th Miles,
Off Jalan Meru, 41050 Klang, Selangor.

TEST REPORT

Sample Description : Latex Examination Polymer Powder Free Glove
 Other Detail : RA/031/02/2020/D1
 Size : Medium
 Quantity Tested : 13 pieces
 Test Conducted : Dimensions
 Test Method : EN 455 Part 2:2015
 Testing Period : 02 Apr 2020 – 15 Apr 2020

Based on submitted samples, the following results obtained :-

Size	M	M	M	M	M	M	M	M	M	M	M	M	M	Median
Width Median: 95±10mm	96	97	96	97	96	95	96	95	96	95	95	97	95	96
Length Median: ≥ 240mm	264	246	260	247	260	256	260	257	262	260	258	257	257	258

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Test Report No. : CRSSA/201150714-CA52027
Company : Top Glove Sdn Bhd
Lot 4969, Jalan Teratai, 6th Miles,
Off Jalan Meru, 41050 Klang, Selangor.

TEST REPORT

Sample Description : Latex Examination Polymer Powder Free Glove
 Other Detail : RA/031/02/2020/D1
 Size : Medium
 Quantity Tested : 13 pieces per each
 Test Conducted : Force at Break During Shelf Life and After Challenge
 Test Method : EN 455 Part 2:2015
 Ageing : 70 ± 2 Deg C for 168 hrs
 Testing Period : 02 Apr 2020 – 15 Apr 2020

SIZE	SAMPLE NO.	Force at Break, N	
		<u>BEFORE AGING</u>	<u>AFTER AGING</u>
M	1	7.5	6.9
	2	8.2	6.8
	3	7.5	7.2
	4	7.8	7.2
	5	7.7	6.4
	6	7.9	6.9
	7	8.1	6.8
	8	7.0	6.8
	9	7.7	6.0
	10	7.3	6.9
	11	8.0	6.8
	12	7.4	6.6
	13	6.4	7.6
Median		7.7	6.8
Requirement		≥ 6.0	≥ 6.0

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Test Report No. : CRSSA/201150717-CA52030
Company : Top Glove Sdn Bhd
Lot 4969, Jalan Teratai, 6th Miles,
Off Jalan Meru, 41050 Klang, Selangor.

TEST REPORT

Sample Description : Latex Examination Polymer Powder Free Glove
Other Detail : RA/031/02/2020/D1
Size : Medium
Quantity Tested : 5 pieces
Test Conducted : Powder Content
Test Method : EN455 Part 3:2015
Testing Period : 02 Apr 2020 – 15 Apr 2020

On testing the samples, the following results were obtained:-

SIZE

M

Average Powder Mass per Glove

0.16 mg

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SHELF LIFE REPORT OF MEDICAL DEVICE (REAL TIME)

Latex Examination Powder Free Gloves (Polymer Coated)

Prepared for

Top Glove Sdn Bhd

VERSION HISTORY		
VERSION	EFFECTIVE DATE	DESCRIPTION OF CHANGE
1.0	August 2015	Complete shelf life report based on Standard EN 455-4:2009.
1.1	January 2020	Revise shelf life report to new format for improvement

Shelf Life Top Glove Sdn. Bhd. Latex Examination Powder Free Gloves (Polymer Coated)

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SHELF LIFE STUDY ANALYSIS: REAL TIME STUDY (EN455)
LATEX EXAMINATION GLOVES-POWDER FREE (POLYMER)

A. Study Background

Reason for study : New standard, EN455-4:2009
Initiate date : August 1, 2010
Initiated by : Nurul 'Ain bt Zulkifle

B. Product Background

Product Name : Latex Examination Glove, Powder Free Polymer
Specification : EN455-1, EN455-2
Features : Ambidextrous, Powder Free, Beaded cuff
Sterilization : None.
Treatment : Polymer coating

C. Test Procedure

Guidance : EN455-4:2009

Descriptor : 3 lots of samples taken from finish goods which there are documented condition of storage . The condition to be documented are:

- i. Date of manufacture
- ii. Length of storage in warehouse
- iii. Location of warehouse
- iv. Storage Temperature
- v. Storage Humidity

D. Test Method

Product Specification : EN455-1, EN455-2

Sampling plan : ISO 2859

a) Test method for Gloves:

i. Freedom from holes : Test method EN455-1

ii. Physical Requirements : Test method EN455-2

Inspection level and sample size:

Item	Inspection level & AQL	Sample size (pieces) /	Acc / Rej (pieces)	Acceptance Criteria
Freedom from holes	G1 AQL 1.5	200	7/8	Meet EN455-1 requirement
Physical Requirement (Dimension)	13 pcs	13	Median value meet EN455-2	Meet EN455-2 requirement
Physical Requirement (Force at break)	13 pcs	13	Force at break = median 6 Newton	Meet EN455-2 requirement
Total glove/set		226		

Estimate gloves piece needed for = 8 times sampling sets x 226 pieces = 1,808 total pieces/ lot

3 lots tested for shelf life study, estimated total quantity = 1,808 pcs x 3 lots = **5,424 pieces**

Note: Set 1: Before aging test, within 96 hours.

Set 2: After 2 months

Set 3: After 6 months

Set 4: After 12 months (1 year)

Set 5: After 24 months (2 years)

Set 6: After 36 months (3 years)

Set 7: After 48 months (4 years)

Set 8: After 60 months (5 years)

Storage condition

Samples are kept at room condition that the temperature and relative humidity is as below (uncontrolled):

a) Temperature = 22-40 °C, average 27± 5 °C.

b) Relative Humidity = 45-80 %, average 65 ± 5 %.

E. Sampling Data

Sampling location : Finish good area / warehouse.
Sampling date : August 12, 2010
Sample time : 9.30 am

3 lots of samples data as below:

Lot Number	Lot 1	Lot 2	Lot 3
Date of manufacture	August 9, 2010	August 9, 2010	August 10, 2010
Length of storage	3 days	3 days	2 days
Location	Warehouse	Warehouse	Warehouse
Product ID	S1L2 260210 C2 (3)	S1L5 260210 C7 (1)	S2L2 270210 C3 (5)
Size	Size M	Size L	Size M
Packaging	Top Glove Examination Inner Box		

F. Testing and Conditioning Apparatus

Test

Water leak : 1000ml semi-auto water-tight test machine
Thickness : MITUTOYO Dial Thickness Gauge (Model: 7301)
Length : SHOWA Steel Ruler 300 mm
Tensile : GoTech Semi Auto Tensile Test Machine
Oven : MEMMERT Lab Oven
Timer (2 minutes) : Omron Digital Timer with siren
Thermo-Hygrometer : TFA Digital Thermo-hygrometer
Electronic Scale : Electronic weighing scale

*Note: The apparatus and other necessary lab appliance above have been calibrated accordingly.

G. Results

FREEDOM FROM HOLES

Specification : Meet EN455-1 requirement
Inspection level : General Inspection Level I, G1
AQL : AQL 1.5
Sample size : 200 pieces
: Accept 7 pieces, Reject 8 pieces
: No leak within 2 minutes
including 1½ inch cuff area
Test location : Water Tight Test Area
Machine no : WTT A

Condition	Lot 1	Lot 2	Lot 3
Initial	Result : 4 holes	Result : 3 holes	Result : 4 holes
Test date : 12/8/10	Status : Passed	Status : Passed	Status : Passed
After 2 months	Result : 5 holes	Result : 4 holes	Result : 5 holes
Test date : 12/10/10	Status : Passed	Status : Passed	Status : Passed
After 6 months	Result : 4 holes	Result : 4 holes	Result : 4 holes
Test date : 12/02/10	Status : Passed	Status : Passed	Status : Passed
After 12 months, 1 year	Result : 4 holes	Result : 4 holes	Result : 4 holes
Test date : 12/8/11	Status : Passed	Status : Passed	Status : Passed
After 24 months, 2 years	Result : 6 holes	Result : 6 holes	Result : 6 holes
Test date : 12/08/12	Status : Passed	Status : Passed	Status : Passed
After 36 months, 3 years	Result : 5 holes	Result : 4 holes	Result : 5 holes
Test date : 12/08/13	Status : Passed	Status : Passed	Status : Passed
After 48 months, 4 years	Result : 5 holes	Result : 5 holes	Result : 5 holes
Test date : 12/08/14	Status : Passed	Status : Passed	Status : Passed
After 60 months, 5 years	Result : 6 holes	Result : 6 holes	Result : 6 holes
Test date : 12/08/15	Status : Passed	Status : Passed	Status : Passed

PHYSICAL PROPERTIES, DIMENSION TEST

Sample size : 13 pieces
 Acceptance : Median of 13 samples comply with EN455-2
 Test Location : QA Room

Condition	Lot 1				
	Palm Width (mm)	Length (mm)	Thickness (mm)		
			Finger	Palm	Cuff
Initial Test date : 12/8/10	96	246	0.13	0.12	0.09
After 2 months Test date : 12/10/10	96	245	0.13	0.12	0.09
After 6 months Test date : 12/02/10	95	244	0.13	0.12	0.09
After 12 months, 1 year Test date : 12/8/11	95	244	0.13	0.12	0.09
After 24 months, 2 year Test date : 12/08/12	95	243	0.14	0.11	0.09
After 36 months, 3 year Test date : 12/08/13	95	242	0.14	0.11	0.09
After 48 months, 4 year Test date : 12/08/14	95	242	0.14	0.10	0.10
After 60 months, 5 year Test date : 12/08/15	95	242	0.14	0.11	0.10
Standard Requirements	80 ± 10	240			
Status	Passed				

Sample Conditon	Lot 2				
	Palm Width (mm)	Length (mm)	Thickness (mm)		
			Finger	Palm	Cuff
Initial Test date : 12/8/10	105	244	0.14	0.11	0.09
After 2 months Test date : 12/10/10	105	244	0.14	0.11	0.09
After 6 months Test date : 12/02/10	105	244	0.14	0.11	0.10
After 12 months, 1 year Test date : 12/8/11	105	243	0.14	0.11	0.09
After 24 months, 2 year Test date : 12/08/12	105	243	0.14	0.11	0.09
After 36 months, 3 year Test date : 12/08/13	105	242	0.14	0.12	0.09
After 48 months, 4 year Test date : 12/08/14	105	243	0.15	0.12	0.09
After 60 months, 5 year Test date : 12/08/15	105	242	0.15	0.12	0.09
Standard Requirements	95 ± 10	240			
Status	Passed				

Sample Conditon	Lot 3				
	Palm Width (mm)	Length (mm)	Thickness (mm)		
			Finger	Palm	Cuff
Initial Test date : 12/8/10	95	244	0.13	0.11	0.09
After 2 months Test date : 12/10/10	95	244	0.13	0.11	0.09
After 6 months Test date : 12/02/10	95	244	0.14	0.11	0.09
After 12 months, 1 year Test date : 12/8/11	95	244	0.13	0.12	0.09
After 24 months, 2 year Test date : 12/08/12	95	243	0.14	0.12	0.09
After 36 months, 3 year Test date : 12/08/13	95	242	0.14	0.11	0.09
After 48 months, 4 year Test date : 12/08/14	95	242	0.14	0.11	0.10
After 60 months, 5 year Test date : 12/08/15	95	242	0.14	0.10	0.10
Standard Requirements	110 ± 10	240			
Status	Passed				

PHYSICAL PROPERTIES, Force at Break test

Specification : Meet EN455-2 requirement, before aging
Sample Size : 13 pieces
Acceptance criteria : Median of 13 samples comply with EN455-2
Location : Tensile Room
Machine no : TM-1

Condition	Lot 1 (N)	Lot 2 (N)	Lot 3 (N)
Initial Test date : 12/8/10	8.2	8.1	9.4
After 2 months Test date : 12/10/10	8.6	8.3	9.3
After 6 months Test date : 12/02/10	8.2	8.1	9
After 12 months, 1 year Test date : 12/8/11	8.1	7.9	8.7
After 24 months, 2 year Test date : 12/08/12	7.8	7.5	7.7
After 36 months, 3 year Test date : 12/08/13	7.3	7.2	7.5
After 48 months, 4 year Test date : 12/08/14	6.9	6.6	7.1
After 60 months, 5 year Test date : 12/08/15	6.5	6.9	7.2
Standard Requirement (min)	6.0	6.0	6.0
Status	Passed	Passed	Passed

H. Analysis

It was found that the test results for all the 3 lots of samples are within specification throughout the 5 years for below tests:

- i. Freedom from holes : Samples passed EN455-1 requirement until 5 years
- ii. Dimension: Samples meet EN455-2 dimension requirement of until 5 years
- iii. Force at break: Samples meet EN455-2 force at break requirement until 5 years

I. Conclusion

The gloves have 5 years expiration date from date of manufacturing.

Prepared by:

Nurul' Ain bt Zulkiflee
Chemist

Verified by:

Ida Zuhana Sahrum
Manager, R&D