TOP GLOVE
TOP QUALITY, TOP EFFICIENCY

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.
+603 3392 1992 +603 3392 1291/8410 +6012 2896 270 sales@topglove.com.my www.topglove.com
BUSINESS DIRECTION : 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	: Biodegradable Nitrile Examination Gloves
Type	: Powder Free
Classification	: Class I, Non Sterile
Brand Name	: PROSENSO™ (EWBIO35M)
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"

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 : 18th October 2022 until 17th October 2023
Basic UDI – DI : 955760101940H5

Name: Pn Noor Akilah Saidin
Designation: RA General Manager

JOB REF NO. : 2019-10-31-002
DATE RECEIVED : OCT 31, 2019
DATE REPORTED: NOV 12, 2019

Test Report No. : CRSSA/191124928-CA24243
Company : Top Glove Sdn Bhd
Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru,
41050 Klang, Selangor.

TEST REPORT

Product Description	:	Biodegradable Nitrile Examination Powder Free, Green
Size	:	Large
Quantity Tested	:	200 pieces
Test Conducted	:	Freedom from holes
Test Method	:	EN455 Part 1:2000
Testing Period	:	31 Oct 2019 – 12 Nov 2019

Based on submitted samples, the following results obtained :-

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

Result : Within AQL

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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/191124928-CA24243
Company : Top Glove Sdn Bhd
Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru,
41050 Klang, Selangor.

TEST REPORT

Product Description	:	Biodegradable Nitrile Examination Powder Free, Green
Size	:	Large
Quantity Tested	:	13 pieces
Test Conducted	:	Dimensions
Test Method	:	EN 455 Part 2:2015
Testing Period	:	31 Oct 2019 – 12 Nov 2019

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: 110±10mm	103	102	102	104	104	104	103	104	104	103	104	103	103	103
Length Median: ≥ 240mm	245	247	253	245	243	247	250	248	250	253	250	253	248	248

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Company : Top Glove Sdn Bhd
Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru,
41050 Klang, Selangor.

TEST REPORT

Product Description	:	Biodegradable Nitrile Examination Powder Free, Green
Size	:	Large
Quantity Tested	:	13 pieces
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	:	31 Oct 2019 – 12 Nov 2019

		Force at Break, N	
SIZE	**SAMPLE NO.**	**BEFORE AGING**	**AFTER AGING**
L	1	5.6	6.8
	2	6.5	7.1
	3	6.6	6.7
	4	7.2	6.9
	5	4.6	7.4
	6	5.4	7.5
	7	5.6	7.2
	8	7.1	7.1
	9	6.0	6.4
	10	5.5	8.0
	11	5.6	6.8
	12	6.6	6.5
	13	6.2	6.6
Median		6.0	6.9
Requirement		≥ 6.0	≥ 6.0

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Test Report No. : CRSSA/191124928-CA24243
Company : Top Glove Sdn Bhd
Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru,
41050 Klang, Selangor.

TEST REPORT

Product Description	:	Biodegradable Nitrile Examination Powder Free, Green
Size	:	Large
Quantity Tested	:	5 pieces
Test Conducted	:	Powder Content
Test Method	:	EN455 Part 3:2015
Testing Period	:	31 Oct 2019 – 12 Nov 2019

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

SIZE	Average Powder Mass per Glove
L	0.4 mg

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Rev 2.0

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SHELF LIFE REPORT OF MEDICAL DEVICE

(Real Time)

Biodegradable Nitrile Exam Glove

Prepared for

Top Glove Sdn Bhd

March 2022

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SHELF-LIFE STUDY ANALYSIS: REAL TIME STUDY (EN 455)
BIODEGRADABLE NITRILE EXAMINATION GLOVES – POWDER FREE

A. Study Background

Reason for study : New Product
Initiate date : 5 October 2018
Initiated by : Nurhazimah binti Zulkarnain

B. Product Background

Product Name : Biodegradable Nitrile Examination Gloves, Powder free
Specification : EN455-1, EN455-2
Features : Ambidextrous, Powder free, Beaded cuff.
Sterilization : None.
Treatment : Chlorination

C. Test Procedure

Guidance : EN455
Description : 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 / Reference Standard

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) / set	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 = 5 times sampling sets x 226 pieces = 1,130 total pieces/ lot
3 lots tested for shelf life study, estimated total quantity = 1,130 pcs x 3 lots = **3,390 pieces**

Note: Set 1: Before aging test, within 96 hours.
Set 2: After 11 months
Set 3: After 17 months
Set 4: After 29 months
Set 5: After 41 months

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 : 5 October 2018
Sample time : 9.30 a.m

3 lots of samples data as below:

Lot Number	Lot 1	Lot 2	Lot 3
Date of manufacture	October 1, 2018	October 1, 2018	October 1, 2018
Length of storage	3 days	3 days	2 days
Location	Warehouse	Warehouse	Warehouse
Size	Size L	Size L	Size L
Packaging	Top Glove Examination 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-Hygorometer :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
Acceptance : Accept 7 pieces, Reject 8 pieces
Acceptance Criteria : No leak within 2 to 3 minutes.
Disregard leakages within 40mm of cuff
Test location : Water Tight Test Area
Machine no : WTT A

Condition	Lot 1		Lot 2		Lot 3	
Initial	Result	: 1 hole	Result	: 2 holes	Result	: 2 holes
Test date : 16/8/18	Status	: Passed	Status	: Passed	Status	: Passed
After 17 months	Result	: 2 holes	Result	: 3 holes	Result	: 3 holes
Test date : 20/3/20	Status	: Passed	Status	: Passed	Status	: Passed
After 29 months	Result	:1 hole	Result	:2 holes	Result	: 3 holes
Test date : 24/3/21	Status	: Passed	Status	: Passed	Status	: Passed
After 41 months	Result	:no hole	Result	2 holes	Result	: 1 holes
Test date : 24/3/22	Status	: Passed	Status	: Passed	Status	: Passed

PHYSICAL PROPERTIES, DIMENSION TEST

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

Sample Conditon	Lot 1				
	Palm Width (mm)	Length (mm)	Thickness (mm)		
			Finger	Palm	Cuff
Initial Test date : 16/8/18	104	240	0.09	0.06	0.06
After 17 months Test date : 20/3/20	105	240	0.09	0.06	0.06
After 29 months Test date: 24/3/2021	105	240	0.09	0.06	0.06
After 41 months Test date : 24/3/22	103	240	0.09	0.06	0.06
Standard Requirement	***110 ± 10***	***240***			
Status	Passed				

Sample Conditon	Lot 2				
	Palm Width (mm)	Length (mm)	Thickness (mm)		
			Finger	Palm	Cuff
Initial Test date : 16/8/18	105	241	0.09	0.06	0.06
After 17 months Test date : 20/3/20	105	240	0.09	0.06	0.06
After 29 months Test date 24/3/21	105	240	0.09	0.06	0.06
After 41 months Test date : 24/3/22	104	240	0.10	0.06	0.06
Standard Requirement	***110± 10***	***240***			
Status	Passed				

Sample Conditon	Lot 3				
	Palm Width (mm)	Length (mm)	Thickness (mm)		
			Finger	Palm	Cuff
Initial Test date : 16/8/18	105	240	0.09	0.06	0.06
After 17 months Test date : 20/3/20	104	241	0.09	0.06	0.06
After 29 months Test date: 24/3/21	104	241	0.09	0.06	0.06
After 41 months Test date : 24/3/22	104	240	0.09	0.06	0.05
Standard Requirement	***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 : 16/8/18	6.7	6.8	6.8
After 17 months Test date : 20/3/20	7.0	6.8	6.8
After 29 months Test date: 24/3/21	6.8	6.2	7
After 41 months Test date: 24/3/22	6.4	6.0	6.2
Standard Requirement	***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 41 months for below tests:
i. Freedom from holes : Samples passed EN455-1 requirement until 41 months
ii. Dimension: Samples meet EN455-2 dimension requirement of until 41 months
iii. Force at break: Samples meet EN455-2 force at break requirement until 41 month

I. Conclusion

The gloves have 41 months expiration date from date of manufacturing.

Prepared by:
Nurhazimah bt Zulkarnain
Executive, R&D

Verified by:
Ida Zuhana Sahrum
Senior Manager, R&D