

Product Validity Validation Report

——EN 455-4

——ASTM D7160

No.: QCPG-81

Version: B / 0

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Title: Vice-General Manager

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Date: September 10, 2017

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Part I: Product validity validation report scheme

1.0 Purpose

Guide experiments, to evaluate the shelf life of Disposable Nitrile Gloves

2.0 Time

2012.9.1 9: 00- 2017.9.1 9: 00

3.0 Reference standard

ISO 188 rubber, vulcanized or thermoplastic - Accelerated Aging and thermal impedance testing

ISO 4684 rubber, vulcanized or thermoplastic - Determination of dimensions of test products and fragments

ISO 2859 sampling plan retrieval of acceptable quality level (AQL) sampling inspection

EN455-4:2009

EN455-1: 2000

EN455-2: 2015

ASTM D6319 :2001

ASTM D7160-2010

ASTM D412-98a

ASTM D 3767:2003(2014)

ASTM D 5151-06

<<Test Method For Nitrile Gloves>>

version No.: B / 0 No.: QCPG-24

4.0 Tested by: Wang Yanxiang

5.0 Using instrument (with calibration report)

Tensile machine No.: FM06002

Thickness gauge No.: LG02004

Watertightness test equipment No.: FC01001

Steel ruler No.: LS01003

6.0 Test method

6.1 Sample selection

Randomly select 3 batches of gloves, and the production lot is:

	Size	Varieties	Lot No.	Time	Quantity (pcs)
The first batch	S	Powder free	12090102	9:00-9:30	3000
The second batch	M	Powder free	12090103	9:00-9:30	3000
The third batch	L	Powder free	12090107	9:00-9:30	3000

6.2 Sample storage

It shall be packed in a box and placed in the sample room. The temperature of the sample room shall be above 25 °C and recorded.

6.3 Tensile test: according to en455-2:2015 , ASTM D412

6.4 Watertightness test

According to en455-1:2000 , ASTM D 5151-06

6.5 Test frequency

6.5.1 Comparison test: a set of values (not aged) shall be tested within 16-96 hours after the product is offline.

6.5.2 Test a set of values (accelerated aging) after 22 ± 0.3 hours at 100 ± 2 °C

6.5.3 On September 1 of each year, according to EN455-1 / EN455-2, 13 samples are taken from each batch to test tensile forces, if the median value is more than 6N, is qualified; 200 samples are taken from each batch to test pinholes and determine by the standard of AQL1.5. According to ASTM D5151-06, ASTM D6319: 2001, 32 samples are taken from each batch to test the tensile strength and elongation, determine by the standard of AQL4.0; 200 samples are taken from each batch to test pinholes and determine by the standard of AQL1.5

6.6 Result determination

Both of them meet the terms of EN455-4 and ASTM D7160, are deemed to be acceptable.

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Part II: Experimental Report

Experimental data:

Project		Batch	The first batch	The second batch	The third batch	Storage temperature, time	Test temperature and humidity
Raw data 2012.9.1 Not aged	EN455 3 mm cutter	Median tension N	6.2	6.2	6.4	20 hour 23°C	23°C 50%RH
	ASTM 6 mm cutter	Tensile strength Mpa	22	23	23	20 hour 23°C	23°C 50%RH
		Elongation%	560	575	565	20 hour 23°C	23°C 50%RH
	Watertightness test		2/200	3/200	3/200	20 hour 23°C	23°C 50%RH
	Determine		Qualified	Qualified	Qualified		
Accelerated aging data 2012.9.5	EN455 3mm cutter	Median tension n	6.5	6.7	6.6	100 ± 2 °C, 22 ± 0.3 hours	23°C 50%RH
	ASTM 6mm cutter	Tensile strength Mpa	23	24	25	100 ± 2 °C, 22 ± 0.3 hours	23°C 50%RH
		Elongation%	480	501	490	100 ± 2 °C, 22 ± 0.3 hours	23°C 50%RH
	Watertightness test		3/200	2/200	4/200	100 ± 2 °C, 22 ± 0.3 hours	
	Determine		Qualified	Qualified	Qualified		
2013.9.1	EN455 3mm cutter	Median tension N	6.5	6.4	6.6	30°C	23°C 50%RH
	ASTM 6mm cutter	Tensile strength Mpa	25	22	24	29°C	23°C 50%RH
		Elongation%	520	510	528	30°C	23°C 50%RH
	Watertightness test		3/200	4/200	2/200		
	Determine		Qualified	Qualified	Qualified		

2014.9.1	EN455 3 mm cutter	Median tension n	6.5	6.6	6.3	29°C	23°C 50%RH
	ASTM 6mm cutter	Tensile strength Mpa	24	23	24	29°C	23°C 50%RH
		Elongation%	512	510	525	29°C	23°C 50%RH
	Watertightness test		4/200	3/200	2/200	29°C	
	Determine		Qualified	Qualified	Qualified		
2015.9.1	EN455 3mm cutter	Median tension n	6.4	6.2	6.5	30°C	23°C 50%RH
	ASTM 6mm cutter	Tensile strength Mpa	23	24	23	30°C	23°C 50%RH
		Elongation%	490	512	501	30°C	23°C 50%RH
	Watertightness test		3/200	4/200	3/200	30°C	
	Determine		Qualified	Qualified	Qualified		
2016.9.1	EN455 3mm cutter	Median tension n	6.4	6.2	6.4	30°C	23°C 50%RH
	ASTM 6mm cutter	Tensile strength Mpa	23	24	23	30°C	23°C 50%RH
		Elongation%	485	498	499	30°C	23°C 50%RH
	Watertightness test		4/200	3/200	3/200	30°C	
	Determine		Qualified	Qualified	Qualified		
2017.9.1	EN455 3mm cutter	Median tension n	6.4	6.2	6.5	30°C	23°C 50%RH
	ASTM 6mm cutter	Tensile strength Mpa	23	24	23	30°C	23°C 50%RH
		Elongation%	480	491	478	30°C	23°C 50%RH
	Watertightness test		3/200	4/200	3/200	30°C	
	Determine		Qualified	Qualified	Qualified		

Note: the tensile strength and elongation in the table are the lowest values of each group of monitoring data

Part III: Conclusion

Conclusion: according to the analysis of experimental data, our company's nitrile gloves meet the requirements of EN455-4 and ASTM D7160 test standards, and the accelerated aging data is basically consistent with the data of gloves stored for five years, and within the scope of index control, the warranty period of nitrile gloves can be determined as five years. And the accelerated aging data of each batch can be used as the basis to determine whether the products meet the five-year shelf life.

(Attached with process inspection data sheet)