

The Shelf Life Validation Testing Report According to EN 455-4

Doc No. :F-QA 01/24

Version: D-01

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Part One: Protocol of Shelf Life Validation Testing Report

1.0 Objective:

In order to guide to complete the shelf life validation test, to ensure the shelf life of the two types of Vinyl Gloves, Powdered and Powder-free

2.0 Time Duration:

From 9 am, September 1, 2012 to 9am September 1, 2017

3.0 Reference Standards:

- ISO 188: 2011 Rubber, vulcanized or thermoplastic -- Accelerated ageing and heat resistance tests
- ISO 4684:2005 Leather -- Chemical tests -- Determination of volatile matter
- ISO2859-1:2009 Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
- EN 455-4: 2009 Medical Glove for Medical Use Part 4: Requirements and testing for shelf life determination
- EN 455-1:2000 Medical Glove for Medical Use Part 1: Requirements and Testing for Freedom from Hole
- EN455-2:2009 Medical Glove for Medical Use Part 2: Requirements and testing for physical properties
- "The SOP for In-process Inspection", Doc# W-QA 01, Version No. A-01

4.0 Test person: Ms. Cui Wenna, QA Engineer

5.0 Instruments (Calibration report attached)

- Dryer, Machine # P-S-14
- Tensile Strength (N) Machine, Machine # P-W4-05
- Gauge, Machine# P-W4-01
- Water Test Equipment , Machine# P-D-12

6.0 Test Method

6.1 Sampling:

To take 3 lots of gloves at random as below:

6.1.1 Product Type A: Disposable Examination Gloves, Vinyl, Powdered, Clear

	Size	Product Item	Lot No.	Time	Quantity (pcs)
1 st lot	S	Powdered	12010611-1	9:00 am	1,300
2 nd lot	M	Powdered	12010811-1	9:00 am	1,300
3 rd lot	L	Powdered	12011011-1	9:00 am	1,300

6.1.2 Product Type B: Disposable Examination Gloves, Vinyl, Powder-free, Clear

	Size	Product Item	Lot No.	Time	Quantity (pcs)
1 st lot	S	Powder Free	12010611-2	9:00 am	1,300
2 nd lot	M	Powder-free	12010811-2	9:00 am	1,300
3 rd lot	L	Powder-free	12011011-2	9:00 am	1,300

6.2 Storage of Samples

Store the samples in the box, using dryer (Machine# P-S-14, at temperature 25°C)

6.3 Tensile Strength (N) Testing:

According to EN455-2: 2009

6.4 Pinhole Testing:

According to EN455-1: 2000

6.5 Frequency of test:

To Test the samples in every September 1 according to 6.3 and 6.4.

6.6 The acceptance standard:

The test result will be accepted if meet the requirement of EN455-4.

Note: The glove are non-sterile and shrink wrapped, so, it is no need to verify the packing.

Part Two: Test Reports

1. Testing Data collecting table for Type A: Disposable Examination Gloves, Vinyl, Powdered, clear

		12010611-1	12010811-1	12011011-1
Raw Data (in 2012)	Tensile Strength (N)	4.1	4.3	4.0
	Pinhole	0/200	1/200	0/200
	Result	Pass	Pass	Pass
1 st year (in 2013)	Tensile Strength (N)	3.8	4.2	4.2
	Pinhole	1/200	0/200	0/200
	Result	Pass	Pass	Pass
2 nd year (in 2014)	Tensile Strength (N)	4.2	4.3	4.1
	Pinhole	0/200	1/200	0/200
	Result	Pass	Pass	Pass
3 rd year (in 2015)	Tensile Strength (N)	4.1	4.2	4.1
	Pinhole	1/200	1/200	0/200
	Result	Pass	Pass	Pass
4 th year (in 2016)	Tensile Strength (N)	4.2	3.9	4.1
	Pinhole	0/200	0/200	1/200
	Result	Pass	Pass	Pass
5 th year (in 2017)	Tensile Strength (N)	4.3	4.0	4.0
	Pinhole	0/200	0/200	1/200
	Result	Pass	Pass	Pass

Conclusion: After collect and analysis the 5 years data, we get the conclusion the powdered vinyl examination comply with the standard of EN455-4, and the shelf lie is 5 years.

2. Testing Data collecting table for Type B: Disposable Examination Gloves, Vinyl, Powder-free, clear

		12010611-4	12010811-4	12011011-4
Raw Data (in 2012)	Tensile Strength (N)	4.1	4.1	4.1
	Pinhole	0/200	0/200	1/200
	Result	Pass	Pass	Pass
1 st year (in 2013)	Tensile Strength (N)	4.1	4.3	4.3
	Pinhole	0/200	1/200	0/200
	Result	Pass	Pass	Pass
2 nd year (in 2014)	Tensile Strength (N)	4.1	3.9	4.1
	Pinhole	0/200	1/200	0/200
	Result	Pass	Pass	Pass
3 rd year (in 2015)	Tensile Strength (N)	4.4	4.1	4.1
	Pinhole	0/200	0/200	1/200
	Result	Pass	Pass	Pass
4 th year (in 2016)	Tensile Strength (N)	4.0	4.3	3.9
	Pinhole	0/200	1/200	1/200
	Result	Pass	Pass	Pass
5 th year (in 2017)	Tensile Strength (N)	4.2	4.3	4.3
	Pinhole	1/200	0/200	0/200
	Result	Pass	Pass	Pass

Conclusion: After collect and analysis the 5 years data, we get the conclusion the powder Free vinyl examination comply with the standard of EN455-4, and the shelf lie is 5 years.

Part Three: The Conclusion

1. **Conclusion:** After collect and analysis the 5 years data for Vinyl Gloves, we get the conclusion both Powdered and Powder-free vinyl gloves comply with the standard of EN455-4, and the shelf lie is 5 years.
2. The test report In process inspection data sheet is attached
3. **Declare:** We hereby to declare that the formulation and process control have not changed since from 2003 till now, we will inform our customer in advance for agreement in case there is any change in later production.

物理性能检测报告 Physical Performance Test Report

Product: Product Type A: Disposable Examination Gloves, Vinyl, Powdered Clear

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Yearly	Lot	Lot#	1	2	3	4	5	6	7	8	9	10	11	12	13	Median	Result	Test By	Date
	Original Data (in 2012)	1st Lot	12010611-1	3.6	4.7	3.9	3.9	4.5	4.5	3.7	4.4	4.1	4.4	4.0	3.7	4.3	3.6	Pass	崔文娜
2nd Lot		12010811-1	4.3	4.4	4.3	3.8	4.4	4.4	4.3	4.5	4.5	4.3	3.9	4.0	3.7	4.3	Pass	崔文娜	01/09/2012
3rd Lot		12011011-1	4.6	3.9	3.8	4.3	4.0	3.7	4.3	3.7	4.1	4.0	3.7	4.4	4.4	4.6	Pass	崔文娜	01/09/2012
1st year (in 2013)	1st Lot	12010611-1	3.8	4.2	3.7	3.7	3.8	4.3	3.9	3.7	3.8	4.2	4.7	3.6	4.1	3.8	Pass	崔文娜	01/09/2013
	2nd Lot	12010811-1	3.9	4.1	4.6	4.5	4.2	4.1	4.3	4.6	4.1	4.3	4.2	4.0	4.3	3.9	Pass	崔文娜	01/09/2013
	3rd Lot	12011011-1	4.6	4.6	4.4	3.8	4.0	4.0	4.5	4.2	4.7	3.7	4.6	3.6	4.2	4.6	Pass	崔文娜	01/09/2013
2nd year (in 2014)	1st Lot	12010611-1	4.6	4.5	3.8	4.3	4.2	4.2	4.7	4.6	4.0	4.2	3.9	3.7	3.6	4.6	Pass	崔文娜	01/09/2014
	2nd Lot	12010811-1	4.0	4.6	4.3	4.5	3.9	3.9	4.0	4.4	4.7	4.5	3.8	3.6	4.6	4.0	Pass	崔文娜	01/09/2014
	3rd Lot	12011011-1	4.3	4.5	3.7	3.9	3.7	4.1	4.1	4.6	3.8	4.3	3.8	4.6	4.2	4.3	Pass	崔文娜	01/09/2014
3rd year (in 2015)	1st Lot	12010611-1	3.7	3.6	3.9	3.9	4.7	3.7	4.3	3.7	4.1	4.1	4.2	4.3	4.6	3.7	Pass	崔文娜	01/09/2015
	2nd Lot	12010811-1	4.1	4.6	4.6	4.0	4.2	3.9	3.8	4.4	4.4	4.5	3.9	4.0	4.7	4.1	Pass	崔文娜	01/09/2015
	3rd Lot	12011011-1	3.8	4.0	4.7	4.4	3.9	4.1	4.1	4.1	4.4	4.5	3.6	4.4	3.7	3.8	Pass	崔文娜	01/09/2015
4th year (in 2016)	1st Lot	12010611-1	4.4	3.9	4.2	4.5	3.7	4.5	3.8	4.2	4.7	4.4	4.3	3.9	4.2	4.4	Pass	崔文娜	01/09/2016
	2nd Lot	12010811-1	3.9	3.7	3.6	4.6	4.0	3.6	4.4	4.1	4.2	4.5	3.9	3.9	3.8	3.9	Pass	崔文娜	01/09/2016
	3rd Lot	12011011-1	3.9	4.5	3.7	3.7	4.2	4.6	4.1	3.8	4.3	4.0	4.1	3.8	4.5	3.9	Pass	崔文娜	01/09/2016
5th year (in 2017)	1st Lot	12010611-1	3.8	4.3	4.6	4.0	4.4	4.4	3.7	4.1	4.5	3.8	4.4	3.9	4.3	3.8	Pass	崔文娜	01/09/2017
	2nd Lot	12010811-1	3.7	4.6	3.9	4.5	4.6	3.8	4.4	4.3	4.0	4.0	3.9	3.7	4.7	3.7	Pass	崔文娜	01/09/2017
	3rd Lot	12011011-1	3.8	4.0	3.7	4.2	4.7	4.3	4.7	3.9	3.7	4.5	4.3	4.0	3.7	3.8	Pass	崔文娜	01/09/2017

Standard: EN455-2:2009.

Median Value: 3.6N

物理性能检测报告 Physical Performance Test Report

Product: Product Type B: Disposable Examination Gloves, Vinyl, Powder-free clear

Doc#: F-QA 01/F23

Yearly	Lot	Lot#	1													Median	Result	Test By	Date								
			2	3	4	5	6	7	8	9	10	11	12	13													
Original Data (in 2012)	1st Lot	12010611-2	4.1	3.7	4.5	3.7	4.4	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	4.1	3.9	Pass	宋丹丹	01/09/2013
	2nd Lot	12010811-2	4.1	4.0	3.7	3.7	3.8	4.3	4.0	4.5	4.5	4.2	4.5	4.3	4.1	4.4	4.2	4.5	4.1	4.5	4.2	4.5	4.0	4.0	Pass	宋丹丹	01/09/2013
	3rd Lot	12011011-2	4.6	3.8	4.3	4.0	4.1	3.6	3.7	4.5	3.8	4.3	4.3	3.7	4.1	4.5	4.3	4.3	4.1	4.5	4.1	4.5	4.1	4.1	Pass	宋丹丹	01/09/2013
1st year (in 2013)	1st Lot	12010611-2	4.1	4.3	4.0	3.8	3.7	4.2	4.3	4.2	4.3	3.8	4.0	4.3	4.2	4.2	4.3	4.1	4.2	3.8	4.0	3.8	4.0	4.0	Pass	宋丹丹	01/09/2013
	2nd Lot	12010811-2	4.2	3.9	4.5	4.4	4.4	3.9	4.5	4.0	4.3	4.5	4.0	4.3	4.0	4.0	4.3	4.3	4.0	4.5	3.7	4.5	4.3	4.3	Pass	宋丹丹	01/09/2013
	3rd Lot	12011011-2	4.2	4.5	4.4	4.4	4.3	4.3	4.3	4.2	4.3	4.6	3.6	4.3	4.3	3.8	4.5	4.3	3.8	4.5	4.3	4.6	4.3	4.3	Pass	宋丹丹	01/09/2013
2nd year (in 2014)	1st Lot	12010611-2	3.8	4.1	4.1	4.2	4.4	4.4	4.5	4.5	3.9	4.5	3.6	3.6	3.9	4.1	3.9	4.1	3.7	4.3	4.3	4.6	4.1	3.9	Pass	宋丹丹	01/09/2014
	2nd Lot	12010811-2	3.7	3.9	3.6	4.6	4.3	4.3	3.9	3.8	3.7	3.8	3.9	4.1	3.7	3.8	4.3	4.3	4.1	4.3	3.8	4.3	4.3	3.9	Pass	宋丹丹	01/09/2014
	3rd Lot	12011011-2	4.7	4.5	4.4	4.7	4.0	4.1	4.1	3.7	4.2	3.9	3.6	3.7	4.1	4.3	4.3	4.3	4.1	4.3	4.3	4.4	4.3	4.3	Pass	宋丹丹	01/09/2014
3rd year (in 2015)	1st Lot	12010611-2	4.6	4.1	4.5	3.8	4.1	4.2	4.5	4.4	4.4	4.0	4.2	4.6	4.5	4.4	4.6	4.5	4.5	4.1	4.4	4.4	4.3	4.2	Pass	宋丹丹	01/09/2015
	2nd Lot	12010811-2	3.7	4.1	3.6	3.8	4.5	4.6	4.4	4.4	4.6	4.3	3.7	4.5	3.7	3.8	4.5	3.8	3.7	3.8	3.8	4.2	4.2	4.2	Pass	宋丹丹	01/09/2015
	3rd Lot	12011011-2	4.3	3.9	4.0	4.4	3.8	3.9	4.4	4.4	4.5	4.0	4.0	4.5	4.1	4.1	4.5	4.1	4.2	4.1	4.1	4.2	4.1	4.1	Pass	宋丹丹	01/09/2015
4th year (in 2016)	1st Lot	12010611-2	4.0	3.7	3.8	4.1	3.9	4.6	4.2	4.2	4.0	3.6	4.1	4.1	3.9	4.2	4.0	4.3	3.9	4.3	4.3	4.2	4.0	4.5	Pass	宋丹丹	01/09/2016
	2nd Lot	12010811-2	4.5	4.5	4.7	4.7	4.4	4.2	4.2	4.5	4.5	3.8	4.3	4.0	4.3	4.3	4.3	4.0	4.3	4.3	3.7	4.3	4.5	4.5	Pass	宋丹丹	01/09/2016
	3rd Lot	12011011-2	3.9	4.3	3.8	3.8	3.7	3.8	3.9	3.9	4.4	4.2	4.2	4.4	4.0	4.3	4.3	4.0	4.3	4.3	3.7	4.3	3.9	3.9	Pass	宋丹丹	01/09/2016
5th year (in 2017)	1st Lot	12010611-2	4.2	4.5	3.9	4.1	4.1	3.6	3.6	3.7	4.6	4.1	4.6	4.6	4.6	4.6	4.6	4.3	4.3	4.4	4.4	4.4	4.0	4.0	Pass	宋丹丹	01/09/2017
	2nd Lot	12010811-2	3.6	4.4	4.5	4.6	4.6	4.6	3.9	4.4	4.5	4.2	4.2	4.5	3.7	4.3	4.2	4.2	3.9	4.3	4.3	4.4	4.4	4.4	Pass	宋丹丹	01/09/2017
	3rd Lot	12011011-2	4.3	4.6	3.8	4.4	3.9	3.9	4.6	4.6	3.7	3.6	4.2	4.2	4.2	4.2	3.8	4.3	4.3	3.9	3.6	4.4	4.4	4.4	Pass	宋丹丹	01/09/2017



















Standard: According to EN455-2:2009.

Median Value: 3.6N

Water Pinhole Test Report

Doc#: F-QA 01/F24

Product: Product Type A: Disposable Examination Gloves, Vinyl, Powdered, clear



















Tested Samples		Leakage pieces	Sample Quantity	Leak Location	Tested by	Date
Original Data (in 2012)	12010611-1	0	200		崔文娜	01/09/2012
	12010811-1	0	200		崔文娜	01/09/2012
	12011011-1	1	200		崔文娜	01/09/2012
1st year (in 2013)	12010611-1	0	200		宋丽华	01/09/2013
	12010811-1	1	200		宋丽华	01/09/2013
	12011011-1	0	200		宋丽华	01/09/2013
2nd year (in 2014)	12010611-1	0	200		宋丽华	01/09/2014
	12010811-1	1	200		宋丽华	01/09/2014
	12011011-1	0	200		宋丽华	01/09/2014
3rd year (in 2015)	12010611-1	0	200		崔文娜	01/09/2015
	12010811-1	0	200		崔文娜	01/09/2015
	12011011-1	1	200		崔文娜	01/09/2015
4th year (in 2016)	12010611-1	0	200		崔文娜	01/09/2016
	12010811-1	1	200		崔文娜	01/09/2016
	12011011-1	1	200		崔文娜	01/09/2016
5th year (in 2017)	12010611-1	1	200		崔文娜	01/09/2017
	12010811-1	0	200		崔文娜	01/09/2017
	12011011-1	0	200		崔文娜	01/09/2017

Standard: According to EN455-1:2000, AQL 1.5, (Re/AC=7, 8)

Water Pinhole Test Report

Doc#: F-QA 01/F24

Product: Product Type B: Disposable Examination Gloves, Vinyl, Powder-free, clear

Tested Samples		Leakage pieces	Sample Quantity	Leak Location	Tested by	Date
Original Data (in 2012)	12010611-2	0	200		崔文娜	01/09/2012
	12010811-2	0	200		崔文娜	01/09/2012
	12011011-2	1	200		崔文娜	01/09/2012
1st year (in 2013)	12010611-2	0	200		宋丽华	01/09/2013
	12010811-2	1	200		宋丽华	01/09/2013
	12011011-2	1	200		宋丽华	01/09/2013
2nd year (in 2014)	12010611-2	1	200		宋丽华	01/09/2014
	12010811-2	0	200		宋丽华	01/09/2014
	12011011-2	0	200		宋丽华	01/09/2014
3rd year (in 2015)	12010611-2	2	200		崔文娜	01/09/2015
	12010811-2	0	200		崔文娜	01/09/2015
	12011011-2	0	200		崔文娜	01/09/2015
4th year (in 2016)	12010611-2	0	200		崔文娜	01/09/2016
	12010811-2	0	200		崔文娜	01/09/2016
	12011011-2	0	200		崔文娜	01/09/2016
5th year (in 2017)	12010611-2	0	200		崔文娜	01/09/2017
	12010811-2	1	200		崔文娜	01/09/2017
	12011011-2	0	200		崔文娜	01/09/2017

Standard: According to EN455-1:2000, AQL 1.5, (Re/AC=7, 8)