



STOP C-19 NITRILE GLOVES

10.01.2020

STOP C-19 NITRILE GLOVES



Carton Of 1000 Nitril Gloves - One Hundred Gloves Per Box



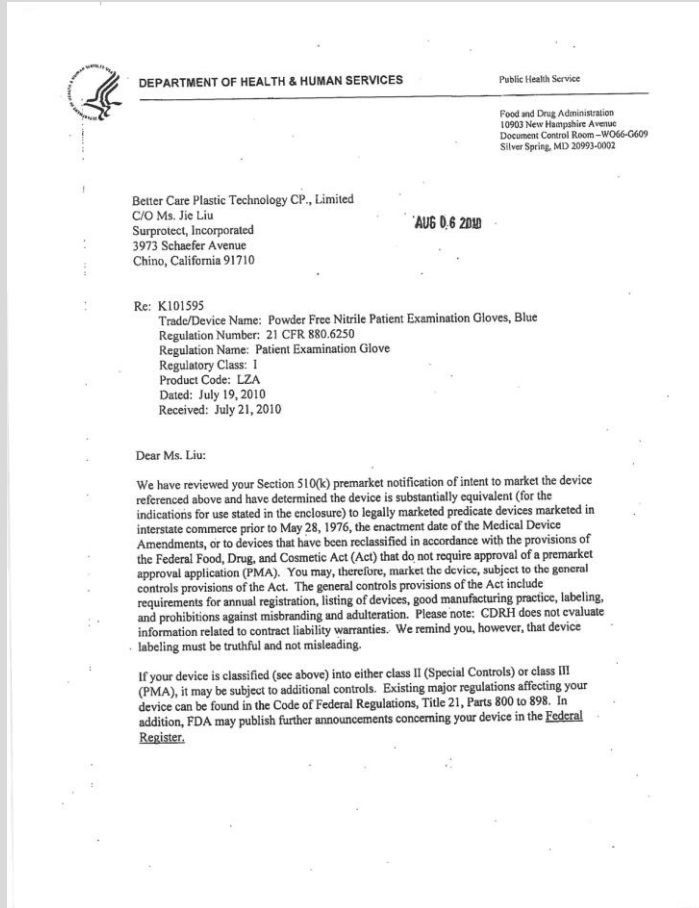
STOP C-19 : Open Box of Nitrile Exam Gloves



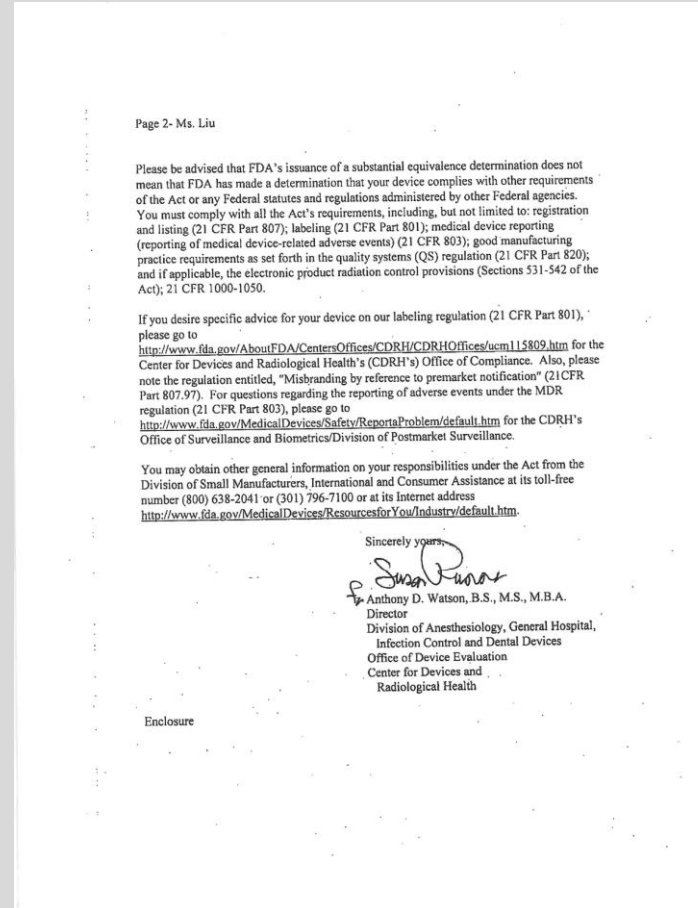
STOP C-19 : Nitrile Exam Glove Stretch



NITRILE GLOVE TESTING



FDA 510K



FDA 510K

FDA 510K Details:

- Regulation Number: 21 CFR 880.6250
- Regulation Name: Patient Examination Glove
- Regulatory Class: 1
- Product Code: LZA
- Dated: August 6, 2010



NITRILE GLOVE PERFORMANCE TESTING

Performance Testing

The Standards used for production of Powder Free Nitrile Patient Examination Gloves (Blue) are mainly based on ASTM D6319-19. In accordance with physical requirements established by the ASTM standard, the following are the physical requirements and dimensional testing results:

Technological Characteristics	Standard/Test/FDA Minimum Guidance	Inspection Level and AQL	Results Summary	Conclusion
Length (mm)	220mm for size XS-S 230mm for size M-XL	S-2, AQL 4.0	XS: 230-238mm	Pass
			S: 234-242mm	
			M: 230-242mm	
			L: 238-244mm	
Width (mm)	XS: 70±10	S-2, AQL 4.0	77-78mm	Pass
	S: 80±10		86-88mm	
	M: 95±10		96-98mm	
	L: 110±10		108-110mm	
	XL: 120±10		116-17mm	
Palm Thickness (mm)	0.05mm minimum	S-2, AQL 4.0	0.085-0.095mm	Pass
Finger Thickness (mm)	0.05mm minimum	S-2, AQL 4.0	0.09-0.105mm	Pass
Tensile Strength (Mpa)				
Before aging	14Mpa minimum	S-2, AQL 4.0	15.7-19Mpa	Pass
After aging	14Mpa minimum	S-2, AQL 4.0	15.2-18.6Mpa	Pass
Ultimate Elongation (%)				
Before aging	500% minimum	S-2, AQL 4.0	500-550%	Pass
After aging	400% minimum	S-2, AQL 4.0	430-530%	Pass
Freedom from Holes	AQL 2.5	G-I, AQL 2.5	0/125, meets AQL 2.5 requirements	Pass
Residual Powder	Not more than 2mg per Glove	N=5	0.5mg	Pass

ASTM D6319-19

Size	Item	Std.	1	2	3	4	5	6	7	8	9	10	11	12	13	
XS	Length (mm) (min)	220	230	234	237	238	234	236	231	236	235	239	237	235	230	
	Width (mm)	70±10	77	77	78	77	77	78	78	77	77	78	77	78	77	
	Thickness (mm) (min)	Finger	0.05	0.06	0.06	0.06	0.07	0.06	0.07	0.06	0.07	0.06	0.07	0.06	0.07	0.06
		Palm	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.06	0.05	0.05	0.05	0.05	0.05
	Before aging	Tensile Strength (Mpa) (min)	14	16.8	17.9	16.8	15.9	16.7	17.8	16.8	16.9	17.5	18.4	18.6	18.9	20
		Elongation % (min)	500	530	520	510	530	510	530	530	530	510	520	500	530	520
	After aging	Tensile Strength (Mpa) (min)	14	16.1	15.9	16.4	15.9	16.7	17.4	17.8	16.9	16.8	16.4	18.6	18.6	18.8
		Elongation % (min)	400	530	530	510	530	510	490	510	500	500	520	510	490	

Size	Item	Std.	1	2	3	4	5	6	7	8	9	10	11	12	13	
S	Length (mm) (min)	220	233	238	237	238	236	236	234	236	236	239	242	239	242	
	Width (mm)	70±10	87	88	87	86	87	86	88	86	88	88	87	87	87	
	Thickness (mm) (min)	Finger	0.05	0.07	0.06	0.06	0.07	0.06	0.07	0.06	0.07	0.06	0.07	0.06	0.07	0.06
		Palm	0.05	0.06	0.05	0.05	0.05	0.05	0.06	0.05	0.05	0.05	0.05	0.05	0.05	0.05
	Before aging	Tensile Strength (Mpa) (min)	14	17.0	16.1	16.4	15.9	16.6	18.1	17.4	17.6	17.0	18.4	17.6	18.4	18.0
		Elongation % (min)	500	510	520	530	540	510	530	530	540	510	500	540	520	510
	After aging	Tensile Strength (Mpa) (min)	14	15.7	15.9	16.4	17.0	16.7	17.4	17.5	16.9	16.8	16.4	18.6	18.6	19.0
		Elongation % (min)	400	480	480	520	430	510	500	410	500	520	500	420	500	530

ASTM. D6319-19, ASTM 0515 | -19 and FDA 1000ml Water Leak Test (21 CFR 800.20).



NITRILE GLOVE PERFORMANCE TESTING

ASTM D5151-19 and FDA
1000ml Water Leak Test
(21 CFR 800.20).

Testing Criteria						Testing Result	Conclusion
Lot Size	Round	Sample Size	Cumulative Sample Size	Accepted Rejection Criteria			
				Accept	Reject		
35,000 and above	1 st	125	125	1	7	125 gloves sampled, zero (0) pcs. leak	Pass
	2 nd	125	250	4	10		
	3 rd	125	375	8	13		
	4 th	125	500	12	17		
	5 th	125	625	17	20		
	6 th	125	750	21	23		
	7 th	125	875	25	26		

Test Method:

As specified in ASTM D6124-06 (2017) Standard Test Method for Residual Powder content on Medical Gloves:

Testing results:

Size	XS	S	M	L	XL
Sample Quantity	5	5	5	5	5
Average Content (mg/glove)	0.55	0.56	0.59	0.60	0.61
Powder Content Criteria: Not to exceed more than 2mg/glove for Powder Free Nitrile Examination Gloves.					

ASTM D6124-06
(2017) Standard Test
Method for Residual
Powder content on
Medical Gloves



NITRILE GLOVE PERFORMANCE TESTING

EN455-1 : 2000 Medical Gloves For Single Use

Part 1 : Requirements & Testing For Physical Holes

EN455-2:2015 Medical Gloves For Single Use

Part 2 : Requirements & Testing For Physical Properties

EN455-3 2015 Medical Gloves For Single Use

Part 3 : Requirements & Testing For Biological Evaluation Clause 4.4 & 4.6

Test Report Number(s):

SHHL1602007536MD-01



The image shows a verification certificate from SGS. At the top right is the SGS logo, which includes a blue bird icon and the letters 'SGS'. The title of the certificate is 'VERIFICATION OF EN 455 CONDITIONAL COMPLIANCE'. The certificate details the following information:

No.:	SHHL1602007536MD-01C
Product Name:	DISPOSABLE NITRILE GLOVE
Style No:	XS, S, M, L, XL, XXL
Applicant:	SHIJIAZHUANG HONGRAY GROUP CO., LTD SOUTH TONGDA RD., EAST DIST., JINZHOU CITY, HEBEI, 052260, CHINA
Manufacturer:	SHIJIAZHUANG HONGRAY GROUP CO., LTD SOUTH TONGDA RD., EAST DIST., JINZHOU CITY, HEBEI, 052260, CHINA
Test Standard:	Sufficient samples of the product have been tested and found to be in conformity with: EN455-1:2000 MEDICAL GLOVES FOR SINGLE USE- PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES EN455-2:2015 MEDICAL GLOVES FOR SINGLE USE- PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES EN455-3:2015 MEDICAL GLOVES FOR SINGLE USE- PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION CLAUSE 4.4 & 4.6
as shown in the Test Report Number(s):	SHHL1602007536MD-01

At the bottom of the certificate, there is a signature of Donna Gu, CSR Manager SBU Section Head at SGS-CSTC Standards Technical Services Co., Ltd. The date is Apr 12, 2016. The certificate also includes a copyright notice and a barcode with the number 16598818.



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