



STOP C-19 NITRILE GLOVES

CONTACT YOUR LOCAL REP

DECEMBER

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

 DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-0609
Silver Spring, MD 20993-0002

Better Care Plastic Technology CP., Limited
C/O Ms. Jie Liu
Surprotect, Incorporated
3973 Schaefer Avenue
Chino, California 91710

AUG 06 2010

Re: K101595
Trade/Device Name: Powder Free Nitrile Patient Examination Gloves, Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: 1
Product Code: LZA
Dated: July 19, 2010
Received: July 21, 2010

Dear Ms. Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

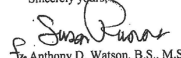
FDA 510K

Page 2- Ms. Liu

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FDA 510K

FDA 510K Details:

- Regulation Number: 21 CFR 880.6250
- Regulation Name: Patient Examination Glove
- Regulatory Class: 1
- Product Code: LZA



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	
			XL: 232-241mm	
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		116-117mm	
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

ASTM. D6319-19, ASTM 0515 I -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		125 gloves sampled, zero (0) pcs. leak	Pass
				Accept	Reject		
35,000 and above	1 st	125	125	1	7		
	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 background features a faint world map. The certificate contains 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

Below the table, there is a signature of Donna Gu, SGS-CHINA SBU Section Head, and the date Apr 12, 2016. A copyright notice states: 'Copyright of this verification is owned by SGS-CSTC Standards Technical Services Co., Ltd. and may not be reproduced other than in full and with the prior approval of the General Manager. This verification is subjected to the governance of the General Conditions of Services, printed overleaf.' At the bottom, it says 'Member of SGS Group (Société Générale de Surveillance)'. There is also a small orange square logo on the left and a barcode at the bottom right with the text 'SGSPAPER 16598818'.



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