

August 26, 2021

Tangshan Lanhai Medical Supplies Co., Ltd. % Ray Wang General Manager Beijing Believe-Med Technology Service Co., Ltd. Rm. 912, Building #15, XiYueHui, No. 5, YiHe North Rd., FangShan District Beijing, Beijing 102401 China

Re: K210898

Trade/Device Name: Disposable Nitrile Examination Gloves (Powder Free, Purple-Blue, Blue) Regulation Number: 21 CFR 880.6250 Regulation Name: Non-Powdered Patient Examination Glove Regulatory Class: Class I, reserved Product Code: LZA Dated: June 1, 2021 Received: June 4, 2021

Dear Ray Wang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <u>https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems</u>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance</u>) and CDRH Learn (<u>https://www.fda.gov/training-and-continuing-education/cdrh-learn</u>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice</u>) for more information or contact DICE by email (<u>DICE@fda.hhs.gov</u>) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Clarence W. Murray III, Ph.D. Assistant Director DHT4B: Division of Infection Control and Plastic Surgery Devices OHT4: Office of Surgical and Infection Control Devices Office of Product Evaluation and Quality Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

510(k) Number *(if known)* K210898

Device Name

Disposable Nitrile Examination Gloves (Powder free, Purple-Blue, Blue)

Indications for Use (Describe)

The Disposable Nitrile Examination Gloves (Powder free, Purple-Blue, Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2023 See PRA Statement below.

510(k) Summary K210898

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K210898

- 1. Date of Preparation: 08/24/2021
- 2. Sponsor

Tangshan Lanhai Medical Supplies Co., Ltd.

South Side of Zhongda Street, East Side of Jinxiu Road, Chengxi Industrial Zone, Luannan County, Tangshan City, Hebei Province, P.R. China 063500 Contact Person: Li Ruidong Position: Manager Tel: +86-15931581811 Fax: +86-315-4155192 Email: 718356353@qq.com

3. Submission Correspondent

Beijing Believe-Med Technology Service Co., Ltd. Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, China,102401 Tel: +86-18910677558 Fax: +86-10-56335780 Email: ray.wang@believe-med.com

4. Proposed Device Identification

Trade Name: Disposable Nitrile Examination Gloves (Powder free, Purple-Blue, Blue) Common Name: NITRILE Patient Examination Gloves (Powder Free) <u>Regulatory Information:</u> Classification: I Product Code: LZA Regulation Number: 21 CFR 880.6250 Review Panel: General Hospital

Indication For Use Statement:

The Disposable Nitrile Examination Gloves (Powder free, Purple-Blue, Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

5. Predicate Device Identification

510(k) Number: K150340

Product Name: POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue) Manufacturer: HEBEI HONGSEN PLASTICS TECHNOLOGY CO., LTD

6. Device Description

The proposed device, Disposable Nitrile Examination Gloves (Powder free, Purple-Blue, Blue) are disposable devices intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

The proposed devices are Powder Free Nitrile Examination Gloves and includes variations of different size and color. The color of the proposed device is Blue and Purple-Blue.

The proposed device is not provided as sterilized

The proposed device is made of Nitrile.

Designation			Size			Tolerance
Designation	XS	S	М	L	XL	Tolerance
Length, mm	220	220	230	230	230	min
Width, mm	70	80	95	110	120	±10
			Thickness, mm:			
Finger 0.05					min	
Palm 0.05					min	
Cuff	Cuff 0.05					min

Table 1 Device	Size	Specifications
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Before	Before Aging After Aging		Pinhole AQL			
Tensile	Ultimate	Tensile	Ultimate			
Strength	Elongation	Strength	Elongation	2.5		
14 MPa, min	500 % min	14 MPa, min	400 % min			

Table 2 Performance and Physical Specifications

The above data of size, performance, and physical specifications of proposed gloves meet all the current specifications listed in the ASTM standard D6319.

7. Comparison of technological characteristics between the subject and predicate devices

	Proposed Device (K210898)	Predicate Device (K150340)					
ITEM	Disposable Nitrile Examination Gloves	POWDER FREE Nitrile GLOVES (White,	Remark				
	(Powder free, Purple-Blue, Blue)	Cobalt Blue, Black, Ice Blue)					
Product Code	LZA	LZA	SAME				
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	SAME				

Table 1 General Comparison

Class	Ι	Ι	SAME
	The Disposable Nitrile Examination Gloves	The POWDER FREE Nitrile GLOVES	SAME
Intended	(Powder free, Purple-Blue, Blue) is a	(White, Cobalt Blue, Black, Ice Blue) is a	
Use/Indication	disposable device intended for medical	disposable device intended for medical	
For Use	purposes that is worn on the examiner's	purposes that is worn on the examiner's	
For Use	hands to prevent contamination between	hands to prevent contamination between	
	patient and examiner.	patient and examiner.	
Powdered or	Powdered free	Powdered free	SAME
Powered free	rowdered free	rowdered free	

Proposed Device (K210898)	Deirection			Size	Size		Tolerance
Disposable Nitrile Examination	Designation	XS	S	М	L	XL	
Gloves (Powder free,	Length, mm	220	220	230	230	230	min
Purple-Blue, Blue)	Width, mm	70	80	95	110	120	±10
				Thickness	, mm:		
	Finger			0.05			min
Palm 0.05					min		
	Cuff	0.05			min		
Predicate Device (K150340)	Size			Tolerance			
POWDER FREE Nitrile	Designation	XS	S	М	L	XL	Tolerance
GLOVES (White, Cobalt Blue,	Length, mm	230	230	230	230	230	min
Black, Ice Blue)	Width, mm	70	80	95	110	120	±10
	Thickness, mm:						
	Finger 0.10-0.12 ±0.03				±0.03		
	Palm 0.08-0.10 Cuff 0.06-0.09				±0.03		
					±0.03		
Remark	Similar						

Table 2 Device Dimensions Comparison

Different Analysis:

The proposed device has different size specification to the predicate device, but all proposed devices are meet the specifications of ASTM D 6319.

ITEM	Proposed Device (K210898) Disposable Nitrile Examination Gloves (Powder free, Purple-Blue, Blue)	Predicate Device (K150340) POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)	Remark
Colorant	Blue, Purple Blue	White, Cobalt Blue, Black, Ice Blue	Different

	Single Us	e	Yes	Yes	SAME
	Before	Tensile Strength	14 MPa, min	15 MPa, min	Different
	Aging	Ultimate Elongation	500 % min	500 % min	SAME
Physical Properties	After	Tensile Strength	14 MPa, min	14 MPa, min	SAME
	Aging Ultimate 400 % min Elongation		400 % min	400 % min	SAME
	Comply w		ply with ASTM D6319	Comply with ASTM D6319	SAME
Freed	dom from	Holes	Be free from holes when tested in accordance with ASTM D5151, AQL 2.5	Be free from holes when tested in accordance with ASTM D5151, AQL 1.5	Different
Powder Content		tent	Less than 2 mg per glove when tested in accordance with ASTM D6124	Meet the requirements of ASTM 6124	SAME

Different Analysis:

The proposed device has different color to the predicate device, this different may causes potential biocompatibility risk, for this risk we conducted the biocompatibility test according to the ISO 10993-10 and ISO 10993-11 and the test results showed that the proposed devices did not induce skin irritation and showed no significant evidence of causing skin sensitization and systemic toxicity response.

Different Analysis:

The proposed device has different Tensile Strength before aging specification to the predicate device, but all proposed device meets the specification requirements of ASTM D 6319.

Different Analysis:

The proposed device has different AQL to the predicate device, but all proposed device meets the specification requirements of ASTM D 6319.

Table 4 Safety Comparison					
		Proposed Device	Predicate Device (K150340)		
		Disposable Nitrile Examination	POWDER FREE Nitrile GLOVES	D. I.	
ITEN	/1	Gloves (Powder free, Purple-Blue,	(White, Cobalt Blue, Black, Ice	Remark	
		Blue)	Blue)		
Material used		Nitrile	Nitrile	SAME	
	Irritation	Under the conditions of the study,	Under the conditions of the study,		
		not an irritant	not an irritant	SAME	
D'	6	Under conditions of the study, not a	Under conditions of the study, not a	SAME	
Biocompatibility	Sensitization	sensitizer.	sensitizer.		
	acute	Under the conditions of the study,	N. (A.,. 111)	Different	
	systemic	there was no evidence of systemic	Not Available	Different	

Table 4 Safety	Comparison
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	toxicity	toxicity from the extract.		
Label and L	abeling	Meet FDA's Requirements	Meet FDA's Requirements	SAME

Different Analysis:

The proposed device has conducted the acute systemic toxicity testing, and the test results showed that there was no evidence of systemic toxicity.

8. Summary of Non-Clinical Testing

Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application. ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.

ASTM D6124-17, Standard Test Method for Residual Powder on Medical Gloves.

ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Test Method	Purpose	Acceptance Criteria	Results
ASTM D5151	Testing for Freedom	Freedom from holes	Blue Color
	from holes	AQL 2.5	No water leakage is inspected form 200
			samples
			Purple-Blue Color
			No water leakage is inspected form 200
			samples
ASTM D6124	Determine the powder	<2.0 mg per glove	Blue Color
	residue for powder free		Residual Powder of Size XS: Average 0.29 mg;
	gloves		Residual Powder of Size S: Average 0.32 mg;
			Residual Powder of Size M: Average 0.39 mg;
			Residual Powder of Size L: Average 0.34 mg;
			Residual Powder of Size XL: Average 0.38mg;
			Purple-Blue Color
			Residual Powder of Size XS: Average 0.33mg;
			Residual Powder of Size S: Average 0.32 mg;
			Residual Powder of Size M: Average 0.32 mg;
			Residual Powder of Size L: Average 0.37 mg;
			Residual Powder of Size XL: Average 0.38mg;
ASTM D412	Testing for Physical	Before Aging	Blue Color
ASTM D573	property characteristics	Tensile Strength: 14 MPa min.	Before Aging
		Ultimate Elongation: 500% min.	Tensile Strength: \geq 19 MPa;

Table 5 Performance Test Results Summary

Testis Strength: 14 MPa min. After Aging Testis Strength: 14 MPa min. After Aging Ultimate Elongation: 400% min. Testile Strength: 2 17.8 MPa; Ultimate Elongation: 400% min. Purple-Blue Color Before Aging Testile Strength: 2 19 MPa; Ultimate Elongation: 2 500% After Aging Testile Strength: 2 10 MPa; Ultimate Elongation: 2 600% AsTM D412 Testing For physical Length: 220 mm min. for size (XS, S); Bite Color Length: 220 mm min. for size (XS, S); Bite Color ASTM D3767 dimensions specification Length: 220 mm min. for size (XS, S); Bite Color ASTM D3767 dimensions specification Length: 220 mm min. for size (XS, S); Bite Color ASTM D3767 dimensions specification Length: 220 mm min. for size (XS, S); Bite Color ASTM D3767 dimensions specification Length: 220 mm min. for size (XS, S); Bite Color ASTM D3767 dimensions specification Length: 210 mm for XS; 80=10 mm for M; 110+10 mm for XS; 80=10 mm for M; 110+10 mm for Tickness of Size XS: 200 mm; Cuff Thickness of Size XS: 200 mm; Vidth '70:10 mm for XL Cuff Thickness of Size S: 200 mm; Palm Thickness of Size S: 20.00 mm; Palm T			Before Aging	Ultimate Elongation: \geq 500%.
ASTM D412 Testing For physical Length: 220 mm min. for size (X, S, S) Blue Color ASTM D412 Testing For physical Length: 220 mm min. for size (X, S, S) Blue Color ASTM D412 Testing For physical Length: 220 mm min. for size (X, S, S) Blue Color ASTM D412 Testing For physical Length: 220 mm min. for size (X, S, S) Blue Color ASTM D412 Testing For physical Length: 220 mm min. for size (X, S, S) Blue Color ASTM D3767 dimensions specification Length: 220 mm min. for size (X, S, S) Blue Color Mith: 70±10 mm for X: Cuff Thickness 20.05 mm; Cuff Thickness 505 Res XS: 20.07 mm; Finger Thickness of Size XS: 20.07 mm; Finger Thickness 0.5 Size X: 20.05 mm; Palm Thickness 20.05 mm; Hith of Size XS: 20.07 mm; Finger Thickness of Size XS: 20.10 mm. All acceptance criteria above meet the requirements in Table 1 Dimensions and Tolermaces of ASTM D6319 Length of Size M: 2240 mm; Width of Size M: 2240 mm; Width of Size M: 212 (95-97) mm; Cuff Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Ength of Size M: 2240 mm; </td <td></td> <td></td> <td></td> <td></td>				
ASTM D412 Testing For physical Length: 220 mm min. for size (X5, S): Blac Color ASTM D412 Testing For physical Length: 220 mm min. for size (X5, S): Blac Color ASTM D3767 dimensions specification Length: 220 mm min. for size (X5, S): Blac Color X1U; Length: 220 mm min. for size (X5, S): Length of Size XS: 220 mm; Width of Size XS: 52.00 mm; X1U; Length: 210 mm for X3; 80±10 mm Finger Thickness of Size XS: 20.07 mm; Finger Thickness: 20.05 mm; Hild of Size XS: 52.010 mm Li 120±10 mm for X1; Length of Size XS: 52.00 mm; Finger Thickness: 20.05 mm; Hild of Size XS: 52.010 mm Li 120±10 mm for XL Cuff Thickness of Size XS: 20.07 mm; Finger Thickness: 20.05 mm; Hild of Size XS: 52.010 mm Li 120±10 mm for XL Cuff Thickness of Size XS: 20.07 mm; Finger Thickness: 20.05 mm; Hild complexes of ASTM D6319 Length of Size XS: 22.00 mm; Finger Thickness of Size XS: 20.00 mm; Finger Thickness of Size XS: 20.00 mm; Length of Size L: 240 mm; Width of Size L: 240 mm; Width of Size XS: 22.00 mm; Finger Thickness of Size XS: 20.00 mm; Length of Size L: 240 mm; Width of Size L: 240 mm; Width of Size L: 240 mm; Finger Thickness of Size XS: 20.00 mm;			e	0.0
ASTM D412 Testing For physical Length: 220 mm min. for size (XS, S); Becore Aging ASTM D3767 Testing For physical Length: 220 mm min. for size (XS, S); Bue Color ASTM D3767 dimensions specification Length: 220 mm min. for size (XS, S); Bue Color ASTM D3767 dimensions specification Length: 230 mm min. for size (X, S); Bue Color Vidth: 70+10 mm for X1; 80+10 mm Length of Size XS: 230 mm; Width: of Size XS: 230 mm; Vidth: 70+10 mm for X1; 100=10 mm for L; 120:10 mm for XL. Cuff Thickness of Size XS: 20.00 mm; Palm Thickness: 20.05 mm; Palm Thickness of Size XS: 20.00 mm; Palm Thickness: 20.05 mm; Palm Thickness of Size S: 20.00 mm; Palm Thickness: 20.05 mm; Palm Thickness of Size S: 20.00 mm; Palm Thickness: 20.05 mm; Palm Thickness of Size S: 20.00 mm; Palm Thickness: 20.05 mm; Palm Thickness of Size S: 20.00 mm; Palm Thickness of Size S: 20.00 mm; Palm Thickness of Size S: 20.00 mm; Palm Thickness: 20.05 mm; Palm Thickness of Size S: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size S: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm;				
ASTM D412 Testing For physical Length: 220 mm min. for size (XS, S); Blue Color ASTM D3767 dimensions specification Length: 220 mm min. for size (XS, S); Blue Color ASTM D3767 dimensions specification Length: 230 mm min. for size (XS, S); Blue Color LU; Length: 230 mm min. for size (XS, S); Blue Color Curf Thickness of Size XS: 230 mm; Width: 70±10 mm for XS; 80±10 mm For S; 95±10 mm for X4; 110±10 mm for Finger Thickness of Size XS: 20.00 mm; Finger Thickness: 20.05 mm; Eength of Size S: 228m; Culf Thickness of Size XS: 20.10 mm. Finger Thickness: 20.05 mm; Palm Thickness of Size XS: 20.07 mm; Finger Thickness of Size S: 20.07 mm; Finger Thickness is 20.05 mm; Palm Thickness of Size S: 20.07 mm; Culf Thickness of Size S: 20.07 mm; All acceptance criteria abve meet the requirements in Table 1 Dimensions and Tolernnces of ASTM D6319 Finger Thickness of Size S: 20.07 mm; Culf Thickness of Size X: 20.06 mm; Palm Thickness of Size X: 20.07 mm; Ength of Size M: 20.07 mm; Culf Thickness of Size X: 20.07 mm; Finger Thickness of Size X: 20.07 mm; Finger Thickness of Size X: 20.07 mm; Finger Thickness of Size X: 20.07 mm; Finger Thickness of Size X: 20.07 mm; Finger Thickness of Size X: 20.07 mm;				
ASTM D3767 Tessing For physical Length: 220 mm min. for size (XS, S); Blue Color ASTM D3767 dimensions specification Length: 220 mm min. for size (XS, S); Blue Color XL); Ultimate Elongation: ≥ 663%. Width: 70±10 mm for XS; 80±10 mm Length of Size XS: ≥ 230 mm; Vicith: 70±10 mm for XL: Length of Size XS: ≥0.06 mm; Uif Thickness: ≥0.05 mm; Palm Thickness of Size XS: ≥0.00 mm; Finger Thickness of Size XS: ≥0.00 mm; Finger Thickness of Size XS: ≥0.00 mm; Finger Thickness: ≥0.05 mm; Uif Thickness: ≥0.05 mm; All acceptance criteria above meet the Palm Thickness of Size XS: ≥0.00 mm; Finger Thickness of Size XS: ≥0.00 mm; Finger Thickness of Size XS: ≥0.00 mm; Finger Thickness: ≥0.05 mm; Quif Thickness of Size S: ≥0.00 mm; Palm Thickness: ≥0.05 mm; Palm Thickness of Size S: ≥0.00 mm; Finger Thickness: ≥0.05 mm; Palm Thickness of Size S: ≥0.00 mm; Palm Thickness: of Size S: ≥0.00 mm; Finger Thickness of Size S: ≥0.00 mm; Palm Thickness of Size S: ≥0.00 mm; Palm Thickness of Size M: ≥0.00 mm; Finger Thickness of Size M: ≥0.00 mm; Finger Thickness of Size M: ≥0.00 mm; Vidth of Size L: 100 min Cuff Thickness of Size M: ≥0.00 mm;				Purple-Blue Color
ASTM D412 Testing For physical Length: 220 mm min. for size (XS, S); Blue Color ASTM D3767 dimensions specification Length: 230 mm min. for size (XS, S); Lungth of Size XS: 220 mm; XL); Length: 220 mm for XS; 80=10 mm Palm Thickness of Size XS: 200 mm; Width of Size XS: 50.06 mm; Vitidh of Size S; 52.06 mm; Palm Thickness: 60.5 mm; Palm Thickness of Size XS: 20.06 mm; Finger Thickness: 20.05 mm; Palm Thickness of Size SS: 52.08 mm; Palm Thickness of Size SS: 52.00 mm; Palm Thickness: 20.05 mm; Palm Thickness of Size SS: 20.06 mm; Palm Thickness of Size SS: 20.07 mm; Finger Thickness: 20.05 mm; Palm Thickness of Size SS: 20.07 mm; Finger Thickness of Size SS: 20.07 mm; Palm Thickness: 20.05 mm; Palm Thickness of Size SS: 20.07 mm; Finger Thickness of Size SS: 20.07 mm; Palm Thickness of ASTM D6319 Length of Size M: 20.06 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm				Before Aging
ASTM D412 Testing For physical Length: 220 mm min. for size (XS, S); Blue Color ASTM D3767 dimensions specification Length: 230 mm min. for size (M, L, XL); Length of Size XS: 230 mm; XL); XL); Width of Size XS: 5743 (75-78) mm; Cuff Thickness of Size XS: 20.06 mm; Width: 70±10 mm for XS; 80±10 mm For \$52 \$52 \$7543 (75-78) mm; Cuff Thickness of Size XS: 20.07 mm; Finger Thickness: 20.05 mm; Length of Size XS: 20.07 mm; Finger Thickness: 20.05 mm; Palm Thickness: 20.05 mm; Palm Thickness of Size XS: 20.00 mm; Palm Thickness of Size SS: 20.10 mm. All acceptance criteria above meet the requirements in Table 1 Dimensions and Tolerances of ASTM D6319 Finger Thickness of Size M: 220 mm; Length of Size M: 2240 mm; Width of Size X: 20.07 mm; Finger Thickness of Size M: 20.07 mm; Palm Thickness of Size M: 20.07 mm; Finger Thickness of Size M: 20.07 mm; Finger Thickness of Size M: 20.06 mm; Palm Thickness of Size M: 20.07 mm; Cuff Thickness of Size M: 20.07 mm; Finger Thickness of Size M: 20.07 mm; Palm Thickness of Size M: 20.07 mm; Finger Thickness of Size M: 20.07 mm; Finger Thickness of Size M: 20.07 mm; Palm Thickness of Size M: 20.07 mm; Finger Thickness of Size M: 20.07 mm; Finger Thickness of Size M: 20.07 mm; <tr< td=""><td></td><td></td><td></td><td>Tensile Strength: \geq 19 MPa;</td></tr<>				Tensile Strength: \geq 19 MPa;
ASTM D412 Testing For physical Length: 220 mm min. for size (XS, S): Blue Color ASTM D3767 dimensions specification Length: 230 mm min. for size (M, L, XL); Blue Color XL, j; Width: 70±10 mm for XS; 80±10 mm Palm Thickness of Size XS: 20.06 mm; Palm Thickness: 50.55 mm; Palm Thickness of Size XS: 20.07 mm; Finger Thickness of Size XS: 20.07 mm; Cuff Thickness: 20.05 mm; Length of Size SS: 20.06 mm; Palm Thickness of Size XS: 20.06 mm; Palm Thickness: 20.05 mm; Length of Size SS: 20.06 mm; Palm Thickness of Size XS: 20.10 mm. All acceptance criteria above meet the requirements in Table 1 Dimensions and Tolerances of ASTM D6319 Finger Thickness of Size S: 20.07 mm; Length of Size M: 240 mm; Width of Size M: 20.06 mm; Palm Thickness of Size M: 20.07 mm; Palm Thickness of Size M: 20.07 mm; Finger Thickness of Size M: 20.07 mm; Finger Thickness of Size M: 20.07 mm; Cuff Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Finger Thickness of Size M: 20.00 mm; Finger Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size L: 20.00 mm; Palm Thickness of Size L: 20.0				Ultimate Elongation: \geq 500%.
ASTM D412 Testing For physical Length: 220 mm min. for size (XS, S): Blue Color ASTM D3767 dimensions specification Length: 230 mm min. for size (M, L, XL); Utimate Elongation: ≥ 463%. ASTM D3767 dimensions specification Length: 230 mm min. for size (M, L, XL); Using the color ASTM D3767 dimensions specification Length: 70±10 mm for XS; 80±10 mm Palm Thickness of Size XS: ≥0.06 mm; Vidth: 70±10 mm for XL; Cuff Thickness of Size XS: ≥0.10 mm. Finger Thickness of Size XS: ≥0.10 mm. L: 120±10 mm for XL; Cuff Thickness: ≥0.05 mm; Palm Thickness of Size S: ≥0.06 mm; Palm Thickness: ≥0.05 mm; Palm Thickness of Size S: ≥0.00 mm. Palm Thickness of Size S: ≥0.00 mm; Palm Thickness: ≥0.05 mm; Palm Thickness of Size S: ≥0.00 mm; Palm Thickness of Size S: ≥0.00 mm; Palm Thickness: ≥0.05 mm; Palm Thickness of Size S: ≥0.00 mm; Palm Thickness of Size S: ≥0.00 mm; Palm Thickness of Size S: ≥0.00 mm; Palm Thickness of Size S: ≥0.00 mm; Finger Thickness of Size S: ≥0.00 mm; Palm Thickness of Size M: ≥0.00 mm; Palm Thickness of Size M: ≥0.00 mm; Palm Thickness of Size M: ≥0.00 mm; Palm Thickness of Size M: ≥0.00 mm; Palm Thickness of Size M: ≥0.00 mm; Palm Thickness of Size L: ≥0.00 mm; <t< td=""><td></td><td></td><td></td><td>After Aging</td></t<>				After Aging
ASTM D412 Testing For physical dimensions specification Length: 220 mm min. for size (XS, S); Length: 230 mm min. for size (X, S); Length: 230 mm min. for size (M, L, XL); Blue Color Midth: 70±10 mm for XS; 80±10 mm for S; 95±10 mm for XS; 80±10 mm for S; 95±10 mm for XL. Cuff Thickness: 20.05 mm; Finger Thickness: 20.05 mm; Palm Thickness: 20.05 mm; All acceptance criteria above meet the requirements in Table 1 Dimensions and Tolerances of ASTM D6319 Length of Size M: 20.00 mm; Finger Thickness of Size S: 20.00 mm; Finger Thickness of Size M: 20.10 mm. Length of Size L: 20.00 mm; Finger Thickness of Size L: 20.00 mm;				Tensile Strength: ≥ 17.1 MPa;
ASTM D3767 dimensions specification Length: 230 mm min. for size (M, L, XL); Length of Size XS: 230 mm; Width: 70±10 mm for XS; 80±10 mm for S; 95±0 mm for XS; 80±10 mm for S; 95±10 mm for XL. Cuff Thickness of Size XS: 20.00 mm; L: 120±10 mm for XL. Cuff Thickness: 20.05 mm; Finger Thickness: 20.05 mm; Palm Thickness: 20.05 mm; Length of Size XS: 20.00 mm; Finger Thickness: 20.05 mm; Palm Thickness: 20.05 mm; Cuff Thickness of Size XS: 20.00 mm; Finger Thickness 20.05 mm; All acceptance criteria above meet the requirements in Table 1 Dimensions and Tolerances of ASTM D6319 Finger Thickness of Size S: 20.00 mm; Length of Size M: 2240 mm; Width of Size M: 22.00 mm; Einger Thickness of Size M: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Length of Size M: 22.00 mm; Finger Thickness of Size M: 20.00 mm; Vidth of Size M: 22.00 mm; Length of Size L: 22.00 mm; Width of Size M: 20.00 mm; Palm Thickness of Size M: 20.10 mm. Length of Size L: 22.00 mm; Length of Size L: 20.00 mm; Palm Thickness of Size M: 20.10 mm. Length of Size L: 20.00 mm; Length of Size L: 20.00 mm; Palm Thickness of Size M: 20.10 mm. Length of Size L: 20.00 mm; Length of Size L: 20.00 mm; Palm Thickness of Size L: 20.00 mm; Palm Thickness of Size L: 20.00 mm; <td></td> <td></td> <td></td> <td>Ultimate Elongation: \geq 463%.</td>				Ultimate Elongation: \geq 463%.
XL);Width of Size XS: 75±3 (75-78) mm; Cuff Thickness of Size XS: 20.06 mm;Width: 70±10 mm for XS; 80±10 mm for S; 95±10 mm for XL.Palm Thickness of Size XS: 20.07 mm;Cuff Thickness: 20.05 mm;Finger Thickness of Size XS: 20.10 mm.L; 120±10 mm for XL.Cuff Thickness: 20.05 mm;Palm Thickness: 20.05 mm;Length of Size S: 52 (28-87) mm;Palm Thickness: 20.05 mm;Vidth of Size S: 85±2 (85-87) mm;Palm Thickness: 20.05 mm;Palm Thickness of Size S: 20.06 mm;Palm Thickness: 20.05 mm;Palm Thickness of Size S: 20.00 mm;Palm Thickness of Size S: 20.05 mm;Palm Thickness of Size S: 20.00 mm;Palm Thickness of Size S: 20.05 mm;Palm Thickness of Size S: 20.00 mm;Palm Thickness of Size S: 20.05 mm;Palm Thickness of Size S: 20.00 mm;Palm Thickness of Size S: 20.05 mm;Palm Thickness of Size S: 20.00 mm;Cuff Thickness of Size S: 20.07 mm;Finger Thickness of Size S: 20.00 mm;Vidth of Size M: 20.07 mm;Finger Thickness of Size M: 20.07 mm;Finger Thickness of Size M: 20.07 mm;Finger Thickness of Size M: 20.00 mm;Palm Thickness of Size L: 20.07 mm;Finger Thickness of Size L: 20.00 mm;Vidth of Size L: 22.00 mm;Vidth of Size L: 22.00 mm;Vidth of Size XL: 22.01 mm.Length of Size XL: 20.01 mm.Length of Size XL: 20.10 mm.Length of Size XL: 20.10 mm.	ASTM D412	Testing For physical	Length: 220 mm min. for size (XS, S);	Blue Color
Vidth: 70±10 mm for XS; 80±10 mmCuff Thickness of Size XS: 20.0 mm; Palm Thickness of Size XS: 20.0 mm; Finger Thickness: 20.05 mm; Palm Thickness: 20.05 mm; Cuff Thickness of Size XS: 20.00 mm; Palm Thickness: 20.05 mm; Palm Thickness of Size XS: 20.00 mm; Cuff Thickness of Size S: 20.00 mm; Palm Thickness of Size M: 20.00 mm; Palm Thickness of Size L: 20.10 mm.	ASTM D3767	dimensions specification	Length: 230 mm min. for size (M, L,	Length of Size XS: \geq 230 mm;
Widh: 70±10 mm for XS; 80±10 mmPalm Thickness of Size XS: ≥0.07 mm;for S; 95±10 mm for XL.Finger Thickness of Size XS: ≥0.10 mm.L; 120±10 mm for XL.Length of Size S: ≥228mm;Cuff Thickness: ≥0.05 mm;Length of Size S: ≥20.66 mm;Palm Thickness: ≥0.05 mm;Cuff Thickness of Size S: ≥0.06 mm;Palm Thickness: ≥0.05 mm;Cuff Thickness of Size S: ≥0.07 mm;Palm Thickness: ≥0.05 mm;Cuff Thickness of Size S: ≥0.06 mm;All acceptance criteria above meet the requirements in Table 1 Dimensions and Tolerances of ASTM D6319Palm Thickness of Size S: ≥0.10 mm.Udth of Size M: ≥0.06 mm;Length of Size M: ≥0.06 mm;Palm Thickness of Size M: ≥0.06 mm;Palm Thickness of Size M: ≥0.07 mm;Finger Thickness of Size M: ≥0.00 mm,Cuff Thickness of Size M: ≥0.00 mm;Palm Thickness of Size M: ≥0.06 mm;Palm Thickness of Size M: ≥0.00 mm;Palm Thickness of Size M: ≥0.10 mm.Length of Size L: ≥240 mm;Width of Size L: ≥240 mm;Width of Size L: ≥0.06 mm;Palm Thickness of Size L: ≥0.07 mm;Finger Thickness of Size L: ≥0.07 mm;Finger Thickness of Size L: ≥0.06 mm;Palm Thickness of Size L: ≥0.07 mm;Palm Thickness of Size L: ≥240 mm;Width of Size L: 20.06 mm;Palm Thickness of Size L: ≥0.06 mm;Palm Thickness of Size L: ≥0.07 mm;Finger Thickness of Size L: ≥0.06 mm;Palm Thickness of Size L: ≥0.06 mm;			XL);	Width of Size XS: 75±3 (75-78) mm;
for \$; 95±10 mm for M; 110±10 mm for L; 120±10 mm for XL.Finger Thickness of Size XS: ≥0.10 mm.Cuff Thickness: ≥0.05 mm;Length of Size S: ≥228mm;Palm Thickness: ≥0.05 mm;Width of Size S: ≥228mm;Palm Thickness: ≥0.05 mm;Cuff Thickness of Size S: ≥0.06 mm;Palm Thickness: ≥0.05 mm;Cuff Thickness of Size S: ≥0.07 mm;Palm Thickness: ≥0.05 mm;Palm Thickness of Size S: ≥0.07 mm;Palm Thickness of ASTM D6319Finger Thickness of Size S: ≥0.10 mm.Tolerances of ASTM D6319Length of Size M: ≥240 mm;Width of Size M: ≥0.06 mm;Palm Thickness of Size M: ≥0.07 mm;Palm Thickness of Size M: ≥0.07 mm;Finger Thickness of Size M: ≥0.06 mm;Palm Thickness of Size M: ≥0.06 mm;Palm Thickness of Size M: ≥0.07 mm;Palm Thickness of Size M: ≥0.07 mm;Finger Thickness of Size M: ≥0.07 mm;Palm Thickness of Size M: ≥0.07 mm;Finger Thickness of Size M: ≥0.07 mm;Palm Thickness of Size M: ≥0.07 mm;Finger Thickness of Size M: ≥0.07 mm;Palm Thickness of Size M: ≥0.07 mm;Finger Thickness of Size M: ≥0.07 mm;Palm Thickness of Size M: ≥0.06 mm;Palm Thickness of Size M: ≥0.07 mm;Palm Thickness of Size M: ≥0.07 mm;Finger Thickness of Size M: ≥0.00 mm;Palm Thickness of Size M: ≥0.01 mm.Palm Thickness of Size M: ≥0.00 mm;Palm Thickness of Size M: ≥0.00 mm;Palm Thickness of Size L: ≥0.00 mm;Palm Thickness of Size M: ≥0.00 mm;Palm Thicknes				Cuff Thickness of Size XS: ≥0.06 mm;
L; 120±10 nm for XL.Length of Size S: 228mm;Cuff Thickness: 20.05 nm;Length of Size S: 228mm;Finger Thickness: 20.05 nm;Width of Size S: 20.06 nm;Palm Thickness: 20.05 nm;Cuff Thickness of Size S: 20.06 nm;All acceptance criteria above meet the requirements in Table 1 Dimensions and Tolerances of ASTM D6319Palm Thickness of Size S: 20.10 mm.Length of Size M: 2040 nm;Length of Size M: 240 nm;Width of Size M: 2040 nm;Cuff Thickness of Size M: 20.06 nm;Palm Thickness of ASTM D6319Length of Size M: 20.07 nm;Cuff Thickness of Size M: 20.07 nm;Cuff Thickness of Size M: 20.07 nm;Finger Thickness of Size M: 20.07 nm;Cuff Thickness of Size M: 20.07 nm;Cuff Thickness of Size M: 20.00 nm;Palm Thickness of Size M: 20.00 nm;Palm Thickness of Size M: 20.00 nm;Finger Thickness of Size M: 20.00 nm;Finger Thickness of Size M: 20.00 nm;Finger Thickness of Size L: 20.00 nm;Palm Thickness of Size L: 20.00 nm;Length of Size L: 20.00 nm;Palm Thickness of Size L: 20.00 nm;Length of Size XL: 241 nm;Width of Size XL: 241 nm;Width of Size XL: 20.00 nm;Cuff Thickness of Size XL: 20.00 nm;Length of Size XL: 20.00 nm;			Width: 70±10 mm for XS; 80±10 mm	Palm Thickness of Size XS: ≥0.07 mm;
Cuff Thickness: $\geq 0.05 \text{ mm};$ Length of Size S: $\geq 228 \text{mm};$ Finger Thickness: $\geq 0.05 \text{ mm};$ Width of Size S: $\geq 2.28 \text{mm};$ Palm Thickness: $\geq 0.05 \text{ mm};$ Cuff Thickness of Size S: $\geq 0.06 \text{ mm};$ All acceptance criteria above meet thePalm Thickness of Size S: $\geq 0.07 \text{ mm};$ requirements in Table 1 Dimensions andFinger Thickness of Size S: $\geq 0.10 \text{ mm}.$ Tolerances of ASTM D6319Length of Size M: $\geq 240 \text{ mm};$ Width of Size M: $\geq 0.06 \text{ mm};$ Palm Thickness of Size M: $\geq 0.00 \text{ mm};$ Palm Thickness of Size M: $\geq 0.00 \text{ mm};$ Palm Thickness of Size M: $\geq 0.00 \text{ mm};$ Palm Thickness of Size M: $\geq 0.10 \text{ mm}.$ Length of Size L: $\geq 240 \text{ mm};$ Width of Size L: $\geq 0.00 \text{ mm};$ Palm Thickness of Size L: $\geq 0.00 \text{ mm};$ Palm Thickness of Size L: $\geq 0.00 \text{ mm};$ Palm Thickness of Size L: $\geq 0.00 \text{ mm};$ Palm Thickness of Size L: $\geq 0.00 \text{ mm};$ Palm Thickness of Size XL: $\geq 241 \text{ mm};$ Width of Size XL: $\geq 0.00 \text{ mm};$			for S; 95±10 mm for M; 110±10 mm for	Finger Thickness of Size XS: ≥0.10 mm.
Finger Thickness: ≥0.05 mm;Width of Size S: 85±2 (85-87) mm;Palm Thickness: ≥0.05 mm;Cuff Thickness of Size S: ≥0.06 mm;All acceptance criteria above meet the requirements in Table 1 Dimensions and Tolerances of ASTM D6319Finger Thickness of Size S: ≥0.10 mm.Length of Size M: ≥240 mm; Width of Size M: ≥240 mm; Cuff Thickness of Size M: ≥0.06 mm; Palm Thickness of Size M: ≥0.07 mm; Finger Thickness of Size M: ≥0.07 mm; Finger Thickness of Size M: ≥0.00 mm;Palm Thickness2007 mm; Cuff Thickness of Size M: ≥0.00 mm; Palm Thickness of Size M: ≥0.00 mm; Finger Thickness of Size M: ≥0.10 mm.Length of Size L: ≥240 mm; Width of Size L: ≥240 mm; Finger Thickness of Size M: ≥0.07 mm; Finger Thickness of Size M: ≥0.00 mm; Finger Thickness of Size L: ≥0.00 mm; Palm Thickness of Size L: ≥0.00 mm; Finger Thickness of Size L: ≥0.00 mm; Cuff Thickness of Size L: ≥0.00 mm; Finger Thickness of Size L: ≥0.00 mm;			L; 120±10 mm for XL.	
Palm Thickness: ≥0.05 mm; Cuff Thickness of Size S: ≥0.06 mm; All acceptance criteria above meet the Palm Thickness of Size S: ≥0.07 mm; requirements in Table 1 Dimensions and Finger Thickness of Size S: ≥0.10 mm. Tolerances of ASTM D6319 Length of Size M: ≥240 mm; Width of Size M: ≥240 mm; Width of Size M: ≥0.06 mm; Palm Thickness of Size M: ≥0.06 mm; Palm Thickness of Size M: ≥0.00 mm; Palm Thickness of Size M: ≥0.00 mm; Palm Thickness of Size M: ≥0.00 mm; Vidth of Size M: ≥0.00 mm; Palm Thickness of Size M: ≥0.00 mm; Palm Thickness of Size M: ≥0.00 mm; Palm Thickness of Size M: ≥0.10 mm. Finger Thickness of Size L: ≥240 mm; Width of Size L: ≥240 mm; Vidth of Size L: ≥240 mm; Palm Thickness of Size M: ≥0.00 mm; Palm Thickness of Size M: ≥0.10 mm. Length of Size L: ≥240 mm; Vidth of Size L: ≥240 mm; Palm Thickness of Size L: ≥0.00 mm; Palm Thickness of Size L: ≥0.01 mm. Length of Size L: ≥0.02 mm; Finger Thickness of Size L: ≥0.10 mm. Length of Size XL: ≥241 mm; Width of Size XL: ≥241 mm; Width of Size XL: ≥0.06 mm;			Cuff Thickness: ≥0.05 mm;	Length of Size S: \geq 228mm;
All acceptance criteria above meet the requirements in Table 1 Dimensions and Tolerances of ASTM D6319Palm Thickness of Size S: ≥ 0.07 mm; Finger Thickness of Size S: ≥ 0.10 mm.Length of Size M: ≥ 240 mm; Width of Size M: ≥ 240 mm; Difference Palm Thickness of Size M: ≥ 0.06 mm; Palm Thickness of Size M: ≥ 0.07 mm; Finger Thickness of Size M: ≥ 0.10 mm.Length of Size M: ≥ 240 mm; Width of Size M: ≥ 0.06 mm; Palm Thickness of Size M: ≥ 0.10 mm.Length of Size L: ≥ 240 mm; Width of Size L: ≥ 240 mm; Palm Thickness of Size M: ≥ 0.10 mm.Length of Size L: ≥ 240 mm; Width of Size L: ≥ 0.06 mm; Palm Thickness of Size L: ≥ 0.00 mm; Finger Thickness of Size L: ≥ 0.10 mm.Length of Size L: ≥ 241 mm; Width of Size XL: ≥ 241 mm; Width of Size XL: ≥ 2.010 mm; Cuff Thickness of Size L: ≥ 0.10 mm.			Finger Thickness: ≥0.05 mm;	Width of Size S: 85±2 (85-87) mm;
requirements in Table 1 Dimensions and Tolerances of ASTM D6319Finger Thickness of Size S: ≥ 0.10 mm.Length of Size M: ≥ 240 mm; Width of Size M: ≥ 240 mm; Cuff Thickness of Size M: ≥ 0.06 mm; Palm Thickness of Size M: ≥ 0.00 mm.Palm Thickness of Size M: ≥ 0.10 mm.Length of Size L: ≥ 240 mm; Width of Size L: ≥ 240 mm; Width of Size L: ≥ 240 mm; Finger Thickness of Size L: ≥ 0.06 mm; Palm Thickness of Size L: ≥ 0.06 mm; Palm Thickness of Size L: ≥ 0.10 mm.Length of Size L: ≥ 0.10 mm.Length of Size L: ≥ 0.06 mm; Palm Thickness of Size L: ≥ 0.10 mm.Length of Size XL: ≥ 241 mm; Width of Size XL: ≥ 241 mm; Width of Size XL: ≥ 241 mm; Width of Size XL: ≥ 0.10 mm.			Palm Thickness: ≥0.05 mm;	Cuff Thickness of Size S: ≥0.06 mm;
Tolerances of ASTM D6319 Length of Size M: ≥ 240 mm; Width of Size M: 95±2 (95-97) mm; Cuff Thickness of Size M: ≥0.06 mm; Palm Thickness of Size M: ≥0.07 mm; Finger Thickness of Size M: ≥0.07 mm; Finger Thickness of Size M: ≥0.10 mm. Length of Size L: ≥ 240 mm; Width of Size L: ≥ 240 mm; Width of Size L: ≥ 240 mm; Width of Size L: ≥ 240 mm; Finger Thickness of Size M: ≥0.10 mm. Length of Size L: ≥ 240 mm; Width of Size L: ≥ 0.06 mm; Palm Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.07 mm; Vidth of Size XL: ≥ 241 mm; Width of Size XL: ≥ 241 mm; Width of Size XL: 115±2 (115-117) mm; Cuff Thickness of Size XL: ≥0.06 mm;			All acceptance criteria above meet the	Palm Thickness of Size S: ≥0.07 mm;
Length of Size M: ≥ 240 mm; Width of Size M: 95±2 (95-97) mm; Cuff Thickness of Size M: ≥0.06 mm; Palm Thickness of Size M: ≥0.07 mm; Finger Thickness of Size M: ≥0.10 mm. Length of Size L: ≥ 240 mm; Width of Size L: ≥ 240 mm; Cuff Thickness of Size M: ≥0.07 mm; Finger Thickness of Size L: ≥0.06 mm; Palm Thickness of Size L: ≥0.06 mm; Palm Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.00 mm; Palm Thickness of Size L: ≥0.00 mm; Vidth of Size XL: ≥241 mm; Width of Size XL: ≥241 mm; Width of Size XL: ≥0.06 mm; Cuff Thickness of Size XL: ≥0.06 mm;			requirements in Table 1 Dimensions and	Finger Thickness of Size S: ≥0.10 mm.
Width of Size M: 95±2 (95-97) mm; Cuff Thickness of Size M: ≥0.06 mm; Palm Thickness of Size M: ≥0.07 mm; Finger Thickness of Size M: ≥0.10 mm. Length of Size L: ≥ 240 mm; Width of Size L: 105±4 (105-109) mm; Cuff Thickness of Size L: ≥0.06 mm; Palm Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.07 mm; Palm Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.00 mm; Length of Size XL: ≥241 mm; Width of Size XL: 115±2 (115-117) mm; Cuff Thickness of Size XL: ≥0.06 mm;			Tolerances of ASTM D6319	
Cuff Thickness of Size M: ≥0.06 mm; Palm Thickness of Size M: ≥0.07 mm; Finger Thickness of Size M: ≥0.10 mm. Length of Size L: ≥ 240 mm; Width of Size L: 105±4 (105-109) mm; Cuff Thickness of Size L: ≥0.06 mm; Palm Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.10 mm. Length of Size XL: ≥ 241 mm; Width of Size XL: ≥ 241 mm; Width of Size XL: ≥ 241 mm; Width of Size XL: ≥ 0.06 mm; Cuff Thickness of Size XL: ≥ 0.06 mm;				Length of Size M: \geq 240 mm;
Palm Thickness of Size M: ≥0.07 mm; Finger Thickness of Size M: ≥0.10 mm. Length of Size L: ≥ 240 mm; Width of Size L: ≥ 240 mm; Width of Size L: 105±4 (105-109) mm; Cuff Thickness of Size L: ≥0.06 mm; Palm Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.10 mm. Length of Size XL: ≥ 241 mm; Width of Size XL: ≥ 241 mm; Width of Size XL: ≥ 115±2 (115-117) mm; Cuff Thickness of Size XL: ≥0.06 mm;				Width of Size M: 95±2 (95-97) mm;
Finger Thickness of Size M: ≥0.10 mm. Length of Size L: ≥ 240 mm; Width of Size L: 105±4 (105-109) mm; Cuff Thickness of Size L: ≥0.06 mm; Palm Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.10 mm. Length of Size XL: ≥ 241 mm; Width of Size XL: ≥ 241 mm; Width of Size XL: ≥ 241 mm; Cuff Thickness of Size XL: ≥ 0.06 mm;				Cuff Thickness of Size M: ≥0.06 mm;
Length of Size L: $\geq 240 \text{ mm}$;Width of Size L: 105 ± 4 (105-109) mm;Cuff Thickness of Size L: $\geq 0.06 \text{ mm}$;Palm Thickness of Size L: $\geq 0.07 \text{ mm}$;Finger Thickness of Size L: $\geq 0.10 \text{ mm}$.Length of Size XL: $\geq 241 \text{ mm}$;Width of Size XL: $\geq 241 \text{ mm}$;Width of Size XL: $\geq 0.06 \text{ mm}$;Cuff Thickness of Size XL: $\geq 0.06 \text{ mm}$;				Palm Thickness of Size M: ≥0.07 mm;
Width of Size L: 105 ± 4 (105-109) mm;Cuff Thickness of Size L: ≥ 0.06 mm;Palm Thickness of Size L: ≥ 0.07 mm;Finger Thickness of Size L: ≥ 0.10 mm.Length of Size XL: ≥ 241 mm;Width of Size XL: ≥ 241 mm;Width of Size XL: ≥ 241 mm;Cuff Thickness of Size XL: ≥ 0.06 mm;				Finger Thickness of Size M: ≥ 0.10 mm.
Width of Size L: 105 ± 4 (105-109) mm;Cuff Thickness of Size L: ≥ 0.06 mm;Palm Thickness of Size L: ≥ 0.07 mm;Finger Thickness of Size L: ≥ 0.10 mm.Length of Size XL: ≥ 241 mm;Width of Size XL: ≥ 241 mm;Width of Size XL: ≥ 241 mm;Cuff Thickness of Size XL: ≥ 0.06 mm;				Length of Size $I \cdot > 240$ mm·
Cuff Thickness of Size L: ≥0.06 mm; Palm Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.10 mm. Length of Size XL: ≥ 241 mm; Width of Size XL: ≥ 241 mm; Cuff Thickness of Size XL: ≥0.06 mm;				6 _ ,
Palm Thickness of Size L: ≥0.07 mm; Finger Thickness of Size L: ≥0.10 mm. Length of Size XL: ≥ 241 mm; Width of Size XL: ≥ 241 mm; Cuff Thickness of Size XL: ≥0.06 mm;				
Finger Thickness of Size L: ≥0.10 mm. Length of Size XL: ≥ 241 mm; Width of Size XL: ≥ 115±2 (115-117) mm; Cuff Thickness of Size XL: ≥0.06 mm;				_ ,
Length of Size XL: ≥ 241 mm; Width of Size XL: 115±2 (115-117) mm; Cuff Thickness of Size XL: ≥0.06 mm;				
Width of Size XL: 115±2 (115-117) mm; Cuff Thickness of Size XL: ≥0.06 mm;				
Cuff Thickness of Size XL: ≥0.06 mm;				Length of Size XL: \geq 241 mm;
				Width of Size XL: 115±2 (115-117) mm;
Palm Thickness of Size XL: ≥0.07 mm;				Cuff Thickness of Size XL: ≥0.06 mm;
				Palm Thickness of Size XL: ≥0.07 mm;
Finger Thickness of Size XL: ≥0.10 mm.				Finger Thickness of Size XL: ≥0.10 mm.

			Purple-Blue Color
			Length of Size XS: \geq 230 mm;
			Width of Size XS: 75±4 (75-79) mm;
			Cuff Thickness of Size XS: ≥0.05 mm;
			Palm Thickness of Size XS: ≥0.07 mm;
			Finger Thickness of Size XS: ≥0.08 mm.
			Length of Size S: \geq 235mm;
			Width of Size S: 85±2 (85-87) mm;
			Cuff Thickness of Size S: ≥0.05 mm;
			Palm Thickness of Size S: ≥0.05 mm;
			Finger Thickness of Size S: ≥0.08 mm.
			Length of Size M: \geq 236 mm;
			Width of Size M: 95±3 (95-98) mm;
			Cuff Thickness of Size M: ≥0.05 mm;
			Palm Thickness of Size M: ≥0.05 mm;
			Finger Thickness of Size M: ≥0.07 mm.
			Length of Size L: \geq 240 mm;
			Width of Size L: 105±3 (105-108) mm;
			Cuff Thickness of Size L: ≥0.05 mm;
			Palm Thickness of Size L: ≥0.06 mm;
			Finger Thickness of Size L: ≥0.08 mm.
			6
			Length of Size XL: \geq 240 mm;
			Width of Size XL: 115±3 (116-118) mm;
			Cuff Thickness of Size XL: ≥ 0.05 mm;
			Palm Thickness of Size XL: ≥0.05 mm;
			Finger Thickness of Size XL: ≥0.08 mm.
ISO 10993-11	Evolute the order int -f	The test article showed no oviderf	
120 10993-11	Evaluate the endpoint of	The test article showed no evidence of	The test article showed no evidence of
	Systemic Cytotoxicity	systemic toxicity from the extract.	systemic toxicity from the extract.
100 10002 10	for biocompatibility		
ISO 10993-10	Evaluate the endpoint of	The response of the test article extract is	The test result showed that the response of the
	irritant for	negligible.	test article extract was categorized as
	biocompatibility		negligible under the test condition.
	Evaluate the endpoint of	The test article showed no evidence of	The test article showed no evidence of causing
	sensitization for	causing delayed dermal contact	delayed dermal contact sensitization in the
	biocompatibility	sensitization.	guinea pig.

9. Summary of Clinical Testing Clinical Testing is not applicable.

10. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue) cleared under K150340.