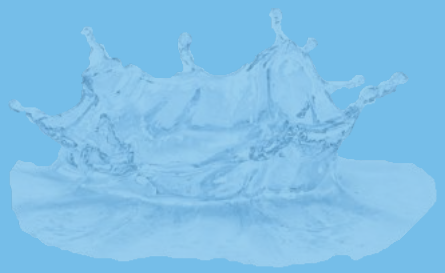
Hederocare

Mit covid-19 hat sich unsere Gesellschaft geändert. Hygienestandards müssen jetzt auch in Zukunft neu definiert werden. Politik, Wirtschaft und Wissenschaft sind sich einig. Nur mit durchdachten Hygienekonzepten verhindern wir sozial sowie ökonomisch Schlimmeres. Wir bieten die elementaren Bausteine zu einem solch notwendigen Hygiene-Engagement!



HEDERO
Care

Kontakt & Infos

Halm Handels UG
Maarstr. 5, 50858 Köln
(0221) 82 82 93 55
halm@halmhandel.de
www.hederocare.de

Hederocare

Hygiene Stylisch neu denken
-
euer Schutz liegt uns am Herzen!

Was wir anbieten

NITRILHANDSCHUHE

Dabei handelt es sich um sterile Untersuchungs- und Schutzhandschuhe zum einmaligen Gebrauch. Perfekt geeignet für die Verwendung im Medizin- und Lebensmittelbereich.

Warum Nitril?

Nitril ist stärker als Latex - es ist bis zu dreimal widerstandsfähiger gegen Durchstiche. Viele medizinische Fachkräfte verlassen sich auf die Festigkeit und Haltbarkeit von Nitrilhandschuhen. Löst keine Latexallergie aus; guter Schutz gegenüber Ölen und Chemikalien; sehr gutes Tastempfinden

Vorteile

Nitrilhandschuhe passen sich den Händen des Benutzers an - bei längerem Tragen, passt sich das Material der Körperwärme der Hände an, wodurch sie bequemer sitzen.

MEDIHANDS

Arbeitsschutz

Die Handschuhe sind als Medizinprodukte der Klasse I und als persönliche Schutzausrüstung der Kategorie III eingestuft. Ihr Design und ihre Kennzeichnung entsprechen den Anforderungen der europäischen Medizinproduktrichtlinie 93/42/EEC und der europäischen Verordnung 2016/425 über persönliche Schutzausrüstung.

DECLARATION OF CONFORMITY

MEDICAL DEVICE REGULATION (EU)2017/745
PERSONAL PROTECTIVE EQUIPMENT REGULATION (EU)2016/425

Legal Manufacturer
Hebei Titans Hongsen Medical Technology Co., Ltd.
Eastern Industrial Zone, Nangong City, Xingtai City,
051800 Hebei, P.R. China

Authorized representative in the EU
MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster
Germany

Brand Owner
MediHands AG
Calendariaweg 2
6405 Immensee
SWITZERLAND

This certificate is valid for the following product:
Non-sterile, nitrile examination and protective gloves for single use, powder-free

Brand: MediHands
Article Name: Nitrile Single Use Gloves
Article No.:
REF No.: TITANFINE HS6213, HS6214, HS6215, HS6216&HS6217
GMDN Code: 56286
UMDNS Code: 11882

Classification (MDR (EU) 2017/745, Annex VI II): Class I, Rule 1.
Classification: Category III according to PPE Regulation (EU) 2016/425

We herewith declare that the above-mentioned product meet the provisions of **Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,** amending Directive 2001 /83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. All Supporting documentations are retained under the premises of the manufacturer. Hebei Titans Hongsen Medical Technology Co., Ltd. is exclusively responsible for the declaration of conformity.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II+ Annex III+ Article 19 of MDR (EU) 2017/745.

Applied standards, common specification, guidance:
EN 455-1 :2000, EN 455-2:2015+A2:2013, EN 455-3:2006, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ASTM D4169-2016, ISO 188:2011, ISO 21171 :2006, ASTM D 6319-10(2015), ASTM D5151-06(2015), ASTM D6124-06 (2017), ASTM D7160-16. MDCG 2019-15.

We hereby declare under sole responsibility that the CE marked product described above conforms with the applicable provisions of **Regulation (EU)2016/425 on Personal Protective Equipment** and is identical to the Personal Protective equipment which is subject to EU Type Examination Certificate number BP 60151281 Sheet 0001 (Module B) according to ANNEX V issued by:

TÜV Rheinland LGA Products GmbH, Notified body 0197
Tilly strasse 2, 90431 Nürnberg, Germany

The products are subject to the procedure set out in ANNEX VII (Module D) of Regulation (EU)2016/425 under the supervision of:

SGS FIMKO OY, Notified body 0598
P.O. Box 30 (Särkiniementie 3), 00211 Helsinki, Finland

Applied standards: *EN 374-1:2016+A1:2018, EN 374-2:2014; EN 374-4:2013, EN 374-5:2016 (Virus), EN ISO 21420:2020*

The declaration is supported by the Quality System approval to ISO 13485:2016 issued by TÜV Rheinland LGA Products GmbH.

Hebei Titans Hongsen Medical Technology Co., Ltd.

_____

Name: Li Yan

Position: Operations Director

Hebei Titans Hongsen Medical Technology Co., Ltd.

Date: 2020/04/21

MEDIHANDS

NITRIL-Einmalhandschuhe

puderfrei

Hergestellt für: Medihands AG
von: GAIA Corporation (Thailand) Limited
712/1 TBI Building, Unit 502, 5th Floor,
Soi Sukhumvit 26 and 28,
Sukhumvit Road, Khlong Tan,
Khlong Toei, Bangkok 10110, Thailand

Hinweise zur Lagerung
- Trocken lagern
- Sonneneinstrahlung vermeiden
- Von Insekten fern halten

Hinweise
- Von scharfen Objekten fern halten, um Einstiche zu vermeiden
- Nach Gebrauch Handschuh nach innen kehren und sofort entsorgen

LOT:
MFG:
EXP:

Elektronik · Reinigung · Industrie · Kosmetik · Gastronomie · allgemeine Pflege

100 HANDSCHUHE NACH GEWICHT CE 0598

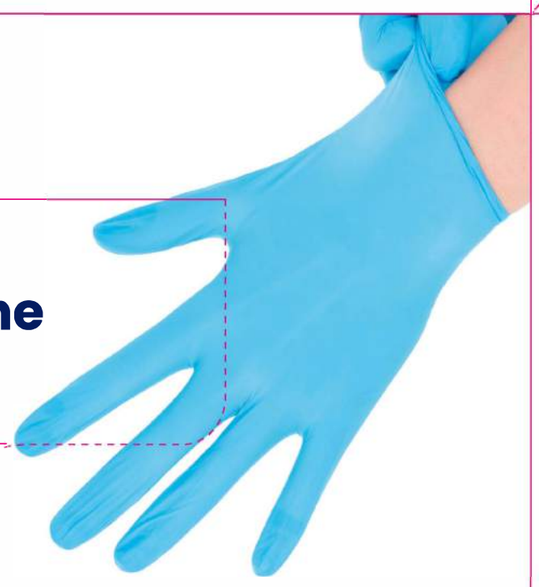
NITRIL-Einmalhandschuhe puderfrei

MEDIHANDS

- für medizinische Zwecke geeignet
- nicht steril
- ideal für Links- und Rechtshänder
- zur einmaligen Anwendung
- guter Griff, texturiert

MEDIHANDS

NITRIL-Einmalhandschuhe puderfrei



- für medizinische Zwecke geeignet
- nicht steril
- ideal für Links- und Rechtshänder
- zur einmaligen Anwendung
- guter Griff, texturiert

100 HANDSCHUHE NACH GEWICHT CE 0598

XL · L · M · S

SCHWARZ · GRÜN · BLAU · WEISS

MEDIHANDS

NITRIL-Einmalhandschuhe puderfrei

CAT III · EN455-1 AQL 1,5 · ISO 13485 · SA80000 POLICY · US-FDA-510 (K)

CE 0598

FOOD SAFE · EN374-1 · EN374-2 · EN374-4 · EN374-5:2016 Virus

NON STERILE · LATEX

REINZEICHNUNG

JOB-NR.:	MEDIHA_2040048
PROJEKT:	MEDIHANDS GLOVES FSCH
KUNDE:	MEDIHANDS
SEGMENT:	
DATUM:	07.12.2020
VERSION:	05

FARBEN

CYAN · MAGENTA · YELLOW · SCHWARZ · PANTONE 485 C · PANTONE 2757 C · STANDZEICHNUNG · TECHN. INFORMATION · TEXTBEREICH

REPROTECHNISCHEARBEITEN, WIE ÜBERFÜLLUNGEN, AUSSPARUNGEN UND ÜBERDRUCKENDE FARBEN SIND IN DIESEM DOKUMENT NICHT BERÜCKSICHTIGT.

LASERAUSDRUCK IST NICHT FARBVERBINDLICH.

IM DIGITALPROOF SIND DIE SONDERFARBEN NUR SIMULIERT.

DRUCK

FORMAT:	393,6 X 372,5 MM
PROGR. VERS.:	ILLUSTRATOR CC
FARBANZAHL:	6
DRUCKVERFAHREN:	XXXX
BEDRUCKSTOFF:	XXXX
LACK:	XXXX
VEREDELUNG:	XXXX

GRÖSSEN

INCI:	XXX PT
FÜLLMENGE/E:	XXXXMM

CREATING IMAGES

EN 455: (1-4)

EN 374 : (1-5)

AQL-Wert: 1,5

CAT III

CE 0598


MEDIHANDS
NITRIL - Einmalhandschuhe
NITRILE - Single Use Gloves
Guantes de NITRILO - desechables
puderfrei | Powder Free | sin polvo
100
HANDSCHUHE NACH GEWICHT
GLOVES BY WEIGHT
GUANTES POR PESO
CE
0598

MEDIHANDS

NITRIL - Einmalhandschuhe, puderfrei
NITRILE - Single Use Gloves, Powder Free
Guantes de NITRILO - desechables, sin polvo

Hinweise zur Lagerung
- Trocken lagern
- Sonneneinstrahlung vermeiden
- Von Insekten fern halten

Storage
- Keep in a dry Place
- Avoid Sunlight
- Keep away from insects

Notas sobre el almacenamiento
- Almacenar en seco
- Evitar la radiación solar
- Mantén alejados de los insectos

Hinweise
- Von scharfen Objekten fern halten, um Einstiche zu vermeiden
- Vor Gebrauch auf Schäden kontrollieren, beschädigte Handschuhe nicht verwenden
- Nach Gebrauch Handschuh nach innen kehren und sofort entsorgen

Directions
- Avoid puncture by sharp objects
- Always check gloves for possible damages before use
- When used, reverse the inside of the glove and dispse of it correctly

Notas
- Manténgase alejado de los objetos punzantes para evitar pinchazos
- Revise siempre los guantes para detectar posibles daños antes de usarlos
- Ponga el guante al revés después de usarlo y deséchalo immediamente

EC REP
MedNet EC-REP GmbH
Borkstrasse 10
48163 Munster,
Germany

Hergestellt für:
Produced for:
Producido para:
MEDIHANDS AG
Calendariaweg 2
6405 Immensee
SWITZERLAND

Hebei Titans Hongsen Medical Technology Co., Ltd.
Eastern Industrial Zone, Nangong City,
Xingtai City, 051800 Hebei
P.R. China

LOT: HS20210313
MFG: 2021.03.13
EXP: 2024.03.13

FFM310-CN08


NITRIL - Einmalhandschuhe
NITRILE - Single Use Gloves
Guantes de NITRILO - desechables
puderfrei | Powder Free | sin polvo
100
MEDIHANDS
MDR
PPE
NITRIL - Einmalhandschuhe, puderfrei
NITRILE - Single Use Gloves, Powder Free
Guantes de NITRILO - desechables, sin polvo
MD
CE
0598
CAT III
AQL
ISO 13485
Declaration of Conformity can downloaded at www.medihands.ch/docs
FOOD SAFE
7 629999 927452

Certificate CN19/42142

The management system of

Hebei Titans Hongsen Medical Technology Co., Ltd.

Eastern Industrial Zone,
Nangong City, Hebei Province, 051800, P.R. China

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

Module D

For the following activities

Manufacture of Nitrile Protective gloves.
(Note: all products marked CE0598 must have a valid EU Type Examination Certificates issued under Module B or a valid EC type-examination certificate issued under Article 10 of the PPE Directive 89/686/EEC.)

This certificate is valid from 7 November 2019 until 21 January 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 November 2021
Issue 1. Certified since 7 November 2019

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Authorised by

SGS FIMKO OY, Notified Body 0598
P.O. Box 30 (Särkiniementie 3),00211 Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Mr. Wenxin Lu
Hebei Titans Hongsen Medical
Technology Co., Ltd.
Eastern Industrial Zone
Nangong City, Xingtai City
051800 HEBEI
CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date August 12, 2020

Application for	**: EU type-examination certificate PPE**
Certificate No.	: BP 60151281 Sheet 0001
Device	: Protective gloves against chemicals and micro-organisms according to EN ISO 374-1+A1:2018
Type	: N48CBL1 XS/SM/MD/LG/XL-Q N50BLK1 XS/SM/MD/LG/XL-Q
Test requirement	: UEReg 425/2016 EN ISO 374-1:2016+A1

Dear Mr. Lu,

The submitted sample of the product has been tested and in this configuration found to be in accordance with the above mentioned requirements.

Enclosed please find your EU-Type-Approval certificate No. BP 60151281 0001.

Kind regards

Certification body

C. Albrecht

Dipl.-Ing. C. Albrecht

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

Z E R T I F I K A T

EU-Baumusterprüfbescheinigung
Verordnung 2016/425/EU
Persönliche Schutzausrüstung

TÜVRheinland®

Registrier Nr.: BP 60151281 0001

Bericht Nr.: 60399914 002

Inhaber:
Hebei Titans Hongsen Medical
Technology Co., Ltd.
Eastern Industrial Zone
Nangong City, Xingtai City
051800 Hebei
P.R. China

Produkt:
Schutzhandschuhe gegen Chemikalien und Mikroorganismen
gemäß EN ISO 374-1+A1:2018

Identifikation:

Einmalhandschuhe	N50BLK1 XS/SM/MD/LG/XL-Q , puderfrei
	N48CBL1 XS/SM/MD/LG/XL-Q , puderfrei
Typ C:	Schutzindex Chemikalie K: NaOH40%, Klasse 6
Material:	Nitril, Wanddicke 0,07-0,08 mm
Größen:	XS(6), S(6,5), M(7,5), L(8,5), XL(9)
Farbe:	schwarz (N50) / blau (N48)

- PSA Kategorie III - überwachungspflichtig Modul C2 -

Die EU-Baumusterbescheinigung bezieht sich auf das o.g. Produkt. Es wird bescheinigt, dass das Produkt den grundlegenden Anforderungen nach Anhang II der Verordnung 2016/425/EU entspricht. Das Zertifikat stellt kein allgemein gültiges Urteil über die Serienfertigung des Produktes dar und berechtigt nicht zur Nutzung eines TÜV Rheinland Prüfzeichens. Der Inhaber ist berechtigt, diese Bescheinigung im Rahmen seiner EU-Konformitätserklärung gemäß Anhang IX zu verwenden.

Gültig bis: 11.08.2025

Benannte Stelle

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Datum 12.08.2020

Dipl.-Ing. C. Albrecht

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Benannt durch die Zentralstelle der Länder für Sicherheitstechnik (ZLS).

Notifiziert unter Nr. 0197 bei der Kommission der Europäischen Gemeinschaft.

CE Die CE-Kennzeichnung darf bei Einhaltung aller zutreffenden EU-Richtlinien angebracht werden. CE

C E R T I F I C A T E

EU Type-Examination Certificate
Regulation 2016/425/EU
Personal Protective Equipment

TÜVRheinland®

Registration No.: BP 60151281 0001

Report No.: 60399914 002

Holder:
Hebei Titans Hongsen Medical
Technology Co., Ltd.
Eastern Industrial Zone
Nangong City, Xingtai City
051800 Hebei
P.R. China

Product:
Protective gloves against chemicals and micro-organisms
according to EN ISO 374-1+A1:2018

Identification:

Disposable gloves N50BLK1 XS/SM/MD/LG/XL-Q , powder-free
N48CBL1 XS/SM/MD/LG/XL-Q , powder-free
Type C: Performance level chemical K: NaOH40%, class 6
Material: nitrile, wall thickness 0,07-0,08 mm
Sizes: XS(6), S(6,5), M(7,5), L(8,5), XL(9)
Colour: black (N50) / blue (N48)
- PPE Category III - obligatory monitoring module C2 -

The EU type-examination certificate refers to the above mentioned product. This is to certify that the product complies with the essential requirements of Annex II of the regulation 2016/425/EU. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity. The holder is entitled to use this certificate in connection with the declaration of conformity in accordance with Annex IX.

Valid till: 11.08.2025

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierstelle

Date 12.08.2020

Dipl.-Ing. C. Albrecht

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Notified by Zentralstelle der Länder für Sicherheitstechnik (ZLS).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

Test Report No. 7191237186-EEC20/01-WBH
dated 26 May 2020

PSB Singapore

Add value.
Inspire trust.

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Gloves submitted by Hebei Titans Hongsen Medical Technology Co., Ltd on 30 Apr 2020.

TESTED FOR:

Hebei Titans Hongsen Medical Technology Co., Ltd
Eastern Industrial Zone, Nangong City,
Hebei Province, China

TEST DATE:

15 May 2020 to 26 May 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Gloves	Blue	2020/04/18	S	5 boxes of 100 pcs for each size	Hebei Titans Hongsen Medical Technology Co., Ltd
2				M		
3				L		
4				XL		

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
No.1 Science Park Drive
Singapore 118221

Phone : +65-6885 1333
Fax : +65-6776 8670
E-mail: enquiries@tuv-sud-psb.sg
www.tuv-sud-psb.sg
Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01
Singapore 118221

PSB Singapore

METHOD OF TEST:

The tests were conducted in accordance with the following test standards:

EN ISO 374-1:2016 Protective gloves against dangerous chemicals and micro-organisms
Part 1: Terminology and performance requirements for chemical risks

- Clause 5.1 General requirements
  (Test method described in EN 420:2003+A1:2009 Protective gloves – General requirements and test methods)

- Clause 5.2 Penetration
  (Test method described in EN 374-2:2014 Protective gloves against dangerous chemicals and micro-organisms – Part 2: Determination of resistance to penetration)

- Clause 5.3 Degradation
  (Test method described in EN 374-4:2019 Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals)

- Clause 5.4 Permeation
  (Test method described in EN 16523-1:2015 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact)

- Clause 6 Marking

- Clause 7 Information supplid by the manufacturer

PSB Singapore

RESULTS:

Table 1: Results for tests according to EN ISO 374-1:2016 Clause 5.1-5.4

Sample: Disposable Nitrile Gloves, Lot No. 2020/04/18

Clause	Tests	Specification	Results			Inferred Result
5.1	General Requirement	Protective gloves against dangerous chemicals shall comply with the requirements given in EN 420:2009, Clause 4, Clause 5 and Clause 7.	Refer to Table 3 for results of EN 420:2009, Clause 4, Clause 5 The submitted glove and packaging not tested to EN 420 Clause 7 Marking and information as requested by client.			Complied Not tested
5.2	Penetration	Protective gloves shall not leak when tested according to EN 374-2:2014, 7.2 and 7.3. 7.2 Air leak test 7.3 Water leak test	Size		-	-
			S		No leakage for both tests	Complied
			M		No leakage for both tests	Complied
			L		No leakage for both tests	Complied
			XL		No leakage for both tests	Complied
5.3	Degradation	The degradation (DR) shall be determined according to EN 374-4 for each chemical claimed in the marking and reported in the user instruction. Tested Chemical: 40% Sodium Hydroxide	Degradation Results (%)			NA
			Size S	Glove 1	-35.0	
				Glove 2	-33.4	
				Glove 3	-31.3	
				Average	-33.2	
				Standard Deviation	1.8	
			Size M	Glove 1	-27.4	NA
				Glove 2	9.2	
				Glove 3	1.1	
				Average	-5.7	
				Standard Deviation	19.3	
			Size L	Glove 1	-4.0	NA
				Glove 2	-31.4	
				Glove 3	-31.0	
				Average	-22.1	
				Standard Deviation	15.7	
			Size XL	Glove 1	-15.9	NA
				Glove 2	-24.3	
				Glove 3	-31.6	
				Average	-23.9	
				Standard Deviation	7.8	

RESULTS (cont'd):

Table 1: Results for tests according to ISO 374-1:2016 (cont'd)

Sample: Disposable Nitrile Gloves, Lot No. 2020/04/18

Clause	Tests	Specification	Results		Inferred Result
5.4	Permeation	Each combination of protective glove/test chemical shall be classified according to Table A (see remark 4), using the results as given in EN 16523-1:2015, 8.5.1.1 or 8.5.1.3 for the normalized breakthrough time. Tested Chemical: 40% Sodium Hydroxide	Breakthrough Time (mins)		Complied
			Glove 1	251	
			Glove 2	289	
			Glove 3	251	
			Mean Value	264	
			Lowest Value	251	
			The breakthrough time occurred after 240 mins, the tested glove is classified as Level 5. No color change was observed on the glove test specimen after the test. *The gloves palm area were taken randomly from any size of "S, M, L and XL." Type of glove: Type C The permeation performance at least level 1 against one test chemical		

Table 2: Results for tests according to ISO 374-1:2016 Clause 6 and 7

Clause	Tests	Specification	Results
6	Marking	Protective gloves against dangerous chemicals shall be marked in accordance with the requirements for protective gloves in EN 420 and with the following: 6.3 Marking of Type C gloves (The permeation level shall be at least Class 1 against minimum of one test chemical): The tested chemical shall be identified by its code letter which shall be marked under the pictogram and a reference to ISO 374-1:2016/ Type C.	NT NT
		Inferred results	Not tested

RESULTS (cont'd):

Table 2: Results for tests according to ISO 374-1:2016 Clause 6 and 7 (cont'd)

Sample: Disposable Nitrile Gloves, Lot No. 2020/04/18

Clause	Tests	Specification	Results
7	Labelling	The information supplied by the manufacturer shall be in accordance with the requirements as defined in EN 420 and the following warnings shall be added in the user instructions:	NT
		- "This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals."	NT
		- "The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm – where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture."	NT
		- "It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation."	NT
		- "When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves"	NT
		- "Before usage, inspect the gloves for any defect or imperfections."	NT
		For reusable gloves, the manufacturer shall provide the relevant instructions for decontamination.	NT
		If there is no information about decontamination, then it is intended for single use only and the following warning shall be added: "For single use only."	NT
		Inferred result	Not tested

RESULTS (cont'd):

Table 3: Results for EN 420:2003+A1:2009

Sample: Disposable Nitrile Gloves, Lot No. 2020/04/18

Test	EN 420:2003+A1:2009 Requirements		Results		Inferred Results
I. Determination of pH Value, pH value	Size	> 3.5 and < 9.5	-		-
	S		7.0		Passed
	M		7.0		Passed
	L		7.0		Passed
	XL		7.0		Passed
II. Sizing, minimum length of glove (mm)	Size	Minimum length of glove (mm)	-		-
	S (6)	220	250		Passed
	M (7)	230	250		Passed
	L (8)	240	260		Passed
	XL (9)	250	270		Passed
III. Dexterity, level of performance	Level of performance	Smallest pin diameter fulfilling test conditions (mm)	-		-
	1	11	Size	-	
	2	9.5	S	5	
	3	8	M	5	
	4	6.5	L	5	
	5	5	XL	5	

REMARKS:

1. For Clause 5.2 Penetration, the test sample will be four gloves of each size, with an overall minimum of 16 gloves per performed test (Air leak test and Water leak test). If one sample fails the penetration test, the test shall be reported as having failed.

2. For Clause 5.3 Degradation, the test specimens for each size will be 3 gloves and 6 specimens will be cut from each glove. For each glove, 3 specimens will be exposed to the challenge chemical (40% Sodium Hydroxide) and 3 specimens will be unexposed. After prepare the specimens, and exposed to 40% Sodium Hydroxide for 1 hour, puncture the specimen and record the peak force required.

3. For Clause 5.4 Permeation, The palm area of the glove sample was mounted between two halves of a test cell. The test cell consisted of a two-compartment cell with 40% Sodium Hydroxide on glove's normal outside surface and Ultrapure Water on the glove's normal inside surface. Testing were carried out at ambient temperature (23°C ± 2°C). The collecting medium were sampled and analysed for 40% Sodium Hydroxide at 10 min (level 1), 30 min (level 2), 60 min (level 3), 120 min (level 4) , 240 min (level 5) and 480 min (level 6). The extracts were then analysed by Ion Chromatography. The results were used to calculate the permeation rate of 40% Sodium Hydroxide through the glove material. Based on the result, the minimum rate of sampling was determined. The tests were repeated at 10 min, 30 min, 60 min, 120 min, 240 min and the sampling interval of 11 min and collected until 480 mins. The extracts were then analysed by Ion Chromatography for the Normalised Permeation Rate. A blank test was carried out exactly with the same procedure except Ultrapure Water was used.

   Note: Chemical transfer referred to the quantity of chemical which had passed through per cm^2 of glove sample at the termination of the test. The thickness of the glove is 0.04mm.

PSB Singapore

REMARKS (cont'd):

4. Table A Classification of Glove Levels According to Breakthrough Time for Clause 5.4 Permeation

Breakthrough Time (mins) *	Permeation performance level
> 10	1
> 30	2
> 60	3
> 120	4
> 240	5
> 480	6

* The breakthrough time is deemed to have occurred when the analytical equipment detects a permeation rate of 1 $\mu g/cm^2/min$.

5. NA: Not applicable for the submitted sample.

6. NT: Not tested.

Lee Dai Yi
Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo 1: Disposable Nitrile Gloves, Lot No. 2020/04/18

Photo 2: Packaging Artwork

PSB Singapore

Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.

2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.

3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.

4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.

5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011

SUBJECT	**Microbiological Analysis**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO., LTD**
CLIENT ADDRESS	EASTERN INDUSTRIAL ZONE, NANGONG CITY, HEBEI PROVINCE, CHINA
TEST PERIOD	30-Apr-2020~13-May-2020
TEST REQUEST	Penetration of Phi-X174 Bacteriophage Test - with reference to ISO 16604-2004, BS EN ISO 374-5:2016

Prepared By **Authorized By**

Bella Xu
(Bella Xu)
Report Drafter

Leo liu
(Leo Liu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
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Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

RECEIPT DATE / TEST DATE

30-Apr-2020/ 30-Apr-2020

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED BY/ ON BEHALF OF THE CLIENTS AS:

Sample Name: Disposable Nitrile Gloves
Batch No./Date: LOT:20/04/18; 2020/04/18
Manufacturer: Hebei Titans Hongsen Medical Technology Co., Ltd

SAMPLE NO.	SAMPLE SPECIFICATION	DESCRIPTION	PHOTOGRAPH
721654161-1	Color: blue Size: S	Gloves	
721654161-2	Color: blue Size: M	Gloves	
721654161-3	Color: blue Size: L	Gloves	
721654161-4	Color: blue Size: XL	Gloves	

TEST METHOD(S)

Penetration of Phi-X174 Bacteriophage Test
- in accordance with BS EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms Part 5: Terminology and performance requirements for micro-organisms risks, 5.3 Protection against viruses. Test method with reference to ISO 16604-2004 Clothing for protection against contact with blood and body fluids -Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X174 bacteriophage

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Regional Head Office:
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No.151 Heng Tong Road Shanghai
200 070 P.R.China

REQUIREMENT

- Exposure Procedure: B

Sampling Size: 75mm×75mm
Negative control: Polyethylene material
Positive control: 0.04 μm microporous membrane
Prior to testing, condition all test specimens and controls for a minimum of 24 hours at (21±5)℃ and 30%~80% relative humidity.

TEST ORGANISM(S)

Bacteriophage ATCC 13706-B1

PROCEDURE

1. Compatibility testing
   1.1. Test three specimens representing each material type to be tested.
   1.2. With the sterile cell placed horizontally on the laboratry bench, insert the specimen in the test cell with the back of the hand and the palm of the hand toward the cell reservoir.
   1.3. Assemble the test cell. Torque the bolts in the test cell to 13.6 N·m each.
   1.4. With the cell remaining in the horizontal position on the laboratory bench, place a 2.0 μL aliquot of the Phi-X174 bacteriophage in bacteriophage nutrient broth, containing a total of 900-1200 PFU, near the middle of each piece of test specimen.
   1.5. Prepare a control by adding a 2.0 μL aliquot from the same suspension directly into 5.0 mL of sterile bacteriophage nutrient broth.
   1.6. After 60 min, quantitatively assay by adding 5.0mL of sterile bacteriophage nutrient broth onto the surface of the specimen.
   1.7. Calculate the ratio of the control assay titer to the test material assay titer using the following equation:
   $$\text{ratio}=\frac{\text{control assay titer (PFU/mL)}}{\text{test material assay titer (PFU/mL)}}=1.1$$
   1.8. Record the initial titer of the Phi-X174 bacteriophage challenge suspension used for the test . ((2±1)x10^8 PFU/mL times the ratio calculated.)

2. Test procedure
   2.1. Prepare the bacteriophage challenge suspension (40-44 mN/m) for the test.
   2.2. With the sterile cell placed horizontally on the laboratry bench, insert the specimen in the test cell with the back of the hand and the palm of the hand toward the cell reservoir.
   2.3. Assemble the test cell. Torque the bolts in the test cell to 13.6 N·m each.
   2.4. Mount the test cell in the test apparatus in a vertical position and close the drain valve.
   2.5. Penetration test: If liquid appears to penetrate through the test specimens at anytime during the test, terminate the test.
      (1) Carefully fill the test cell reservoir with approximately 60 mL of the Phi-XI74 bacteriophage challenge suspension
      (2) Step1: Observe for 5 min at 0 psi.
      Step2: Slowly increase the pressure to 2.0 psi at the rate of no more than 0.5 psi/s, keep the pressure at 2.0 psi, observe for 1 min.
      Step3: Slowly decrease the pressure to 0 psi at the rate of no more than 0.5 psi/s, observe for 54 min.
      (3) At the end of the time period, open the drain valve and drain the test cell of the bacteriophage challenge suspension. Dilute and assay the bacteriophage concentration.
   2.6. Specimen surface assay procedure
      (1) With the sterile cell placed horizontally on the laboratory bench. Slowly add 5.0 mL of sterile bacteriophage nutrient broth onto the exposed surface of the specimen.
      (2) Gently swirl the test cell for approximately 1 min. Assay the liquid soon after collecting.
   2.7. Remove the specimen from the test cell and prepare the test cell for sterilization.

3. Test controls
   3.1. The negative control was negative for bacteriophage penetration.
   3.2. The positive control was positive for bacteriophage penetration.
   3.3. Record the final titer of the bacteriophage challenge at the conclusion of the 60 min test.

TEST RESULT(S)

Test Items		Initial titer PFU/ml	Final titer PFU/ml	Test Results				
				Step1	Step2	Step3	Assay titer (PFU/ml)	Pass/Fail
Penetration of Phi-X174 Bacteriophage	Control(+)	$1.9x10^8$	$1.9x10^8$	None Seen	Seen	-	-	Acceptable
	Control(-)	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Acceptable
	721654161 -1①	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -1②	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -1③	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -2①	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -2②	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -2③	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -3①	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -3②	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -3③	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -4①	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -4②	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -4③	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass

Note:
1.PFU: Plaque Forming Unit.
2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
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Regional Head Office:
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No.151 Heng Tong Road Shanghai
200 070 P.R.China

Test Report

No.: QDHL2005003791MD_EN Date: MAY.21,2020 Page: 1 of 5

Client name	:	HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD.
Client address	:	EASTERN INDUSTRIAL ZONE, NANGONG CITY, XINGTAI CITY, HEBEI, CHINA
Sample Description	:	SINGLE-USE NITRILE PATIENT EXAMINATION GLOVES (BLUE)
Lot No.	:	NOT PROVIDED
Lot Size	:	NOT PROVIDED
Sample Quantity	:	S: 200PCS, M: 200PCS, L: 200PCS, XL: 200PCS
Style/ Item No.	:	S, M, L, XL
Manufacture	:	HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD.
Country of Origin	:	CHINA
Country of Destination	:	EUROPE & USA

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

****

Sample Receiving Date	:	MAY.06,2020
Test Performing Date	:	MAY.06,2020 TO MAY.21,2020
SGS Ref. No.	:	TJHL2004002164MD

****

Test Requested	Result
1. BS EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE – PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES (CLAUSE 5.1) (FOR SIZE S ONLY)	Pass
2. BS EN 455-2:2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES (CLAUSE 4.2, 4.3) (FOR SIZE L ONLY)	Pass
3. BS EN 455-2:2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES (CLAUSE 5.2, 5.3) (FOR SIZE XL ONLY)	Pass
4. BS EN 455-3:2015 MEDICAL GLOVES FOR SINGLE USE—PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION (CLAUSE 4.4) (FOR SIZE M ONLY)	Pass

Remark: - Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

SGS-CSTC Standards
Technical Services (Qingdao)
Co., Ltd.

scan to see the report
QDHL2005003791MD

Jessica Gao
Approved Signatory

Test Conducted:

1. **BS EN 455-1:2000 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes**

Number of test sample	:	200 Pieces
Sample size	:	S
Number of non-conforming gloves	:	0

Clause	Test Items	Result
5	Watertightness test for detection of holes	---
5.1	Referee testing	Pass (See note 1)

Note : 1 Sample quantity: 200pcs, AQL:1.5, Ac:7, Re:8, Found:0.
The sample selecting amount for this clause is deviated to 200 pcs as assessed by SGS.

2. **BS EN 455-2:2015 Medical gloves for single use – Part 2: Requirements and testing for physical properties**

Number of test sample	:	26 Pieces
Type	:	Examination/procedure gloves b)
Size	:	Examination/procedure gloves: L, XL

Clause	Test Items	Result
4	Dimensions (for size L only)	---
4.2	Length	Pass (See result 1)
4.3	Width	Pass (See result 1)
5	Strength (for size XL only)	---
5.2	Force at break	Pass (See result 2)
5.3	Force at break after challenge testing	Pass (See result 2)

Result 1: Dimensions

Size	L	
No.	Length (mm)	Width (mm)
1	285	109
2	290	109
3	284	109
4	290	109
5	289	109
6	289	108
7	290	110
8	287	108
9	285	109
10	286	109
11	287	109
12	286	109
13	289	108
Standard requirement	≥240	110±10
Median value	287	109

Result 2: Strength

Size: XL			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	7.8	1	7.2
2	7.7	2	7.6
3	7.9	3	7.7
4	7.1	4	6.9
5	8.3	5	7.4
6	7.4	6	6.9
7	7.5	7	7.0
8	7.2	8	6.6
9	7.8	9	7.6
10	7.0	10	7.0
11	7.6	11	7.3
12	7.5	12	7.1
13	7.7	13	7.3
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	7.6	Median value	7.2

3. BS EN 455-3:2015 Medical gloves for single use – Part 3: Requirements and testing for biological evaluation

Number of test sample	:	5 Pieces
Sample size	:	M
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves

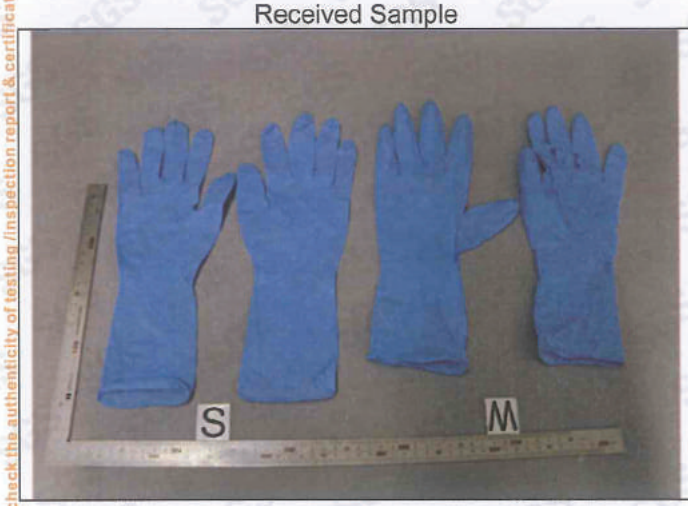
Clause	Test Items	Result
4.4	Powder-free gloves	Pass (See note 1)

Note : 1 Test according to EN ISO 21171:2006, the average mass of powder per glove is 0.02mg. (Requirement: ≤2mg per powder-free glove)

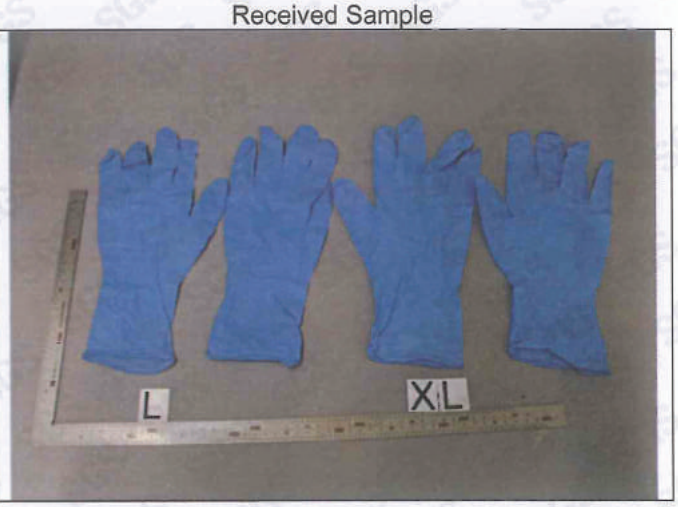
Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

Sample Photo:

Received Sample



Received Sample



SGS authenticate the photo on original report only

End of Report

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1430839**

Certificate Holder:

Hebei Titans Hongsen Medical Technology Co., Ltd.
Unified Social Credit Code: 91130581054013624U
Registration Address: Eastern Industrial Accumulation Zone, Nangong City, 051800 Hebei, P. R. China
Operation Address: Dongjin Street, Eastern Industrial Accumulation Zone, Nangong City, 051800 Hebei, P. R. China

Scope: Manufacturing and Sales of Single-use Medical Rubber Examination Gloves

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2021-04-09 until 2024-04-08.
It remains valid subject to satisfactory surveillance audits.
First certification 2015
This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2021-03-15

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Hebei Titans Hongsen Medical Technology Co., Ltd.
Eastern Industrial Zone
Nangong City, Xingtai City
051800 Hebei
China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Single-use Patient Examination Gloves

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-06-27
Certificate Registration No.:	SX 60129395 0001
An audit was performed. Report No.:	16804328 004
This Certificate is valid until:	2021-05-10

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-06-27

X. Ren

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

April 10, 2018

Hebei Titans Hongsen Medical Technology Co., Ltd.

SUBJECT: Permeation testing per ASTM D 6978 on sample submitted by the above company.

RECEIVED: One glove type identified as Low Weight Powder Free Blue Nitrile Examination Gloves; Lot# 18030515A0501.

TESTING CHEMOTHERAPY DRUGS:

Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Bleomycin	Teva; Lot# 31321906B; Expiration 09/2019
Busulfan	Sigma Aldrich; CAS# 55-98-1; Lot# BCBS3842V
Carboplatin	Teva; Lot# 16H18KA; Expiration 08/2018
Carmustine (BCNU)	Sigma Aldrich; Lot# 018M4057V; Expiration 03/2019
Cisplatin	WG Critical Care; Lot# 7L04842; Expiration 04/2019
Cyclophosphamide	Sandoz Inc; Lot# 17101325; Expiration 10/12/2019
Cytarabine	Sigma Aldrich; Lot# 060M5051V; Expiration 09/2018
Cytovene (Ganciclovir)	Sigma Aldrich; Lot# 097M4004V; Expiration 12/2018
Dacarbazine (DTIC)	Teva; Lot# 31322092B; Expiration 11/2019
Daunorubicin	Sigma Aldrich; Lot# 125M4750V; Expiration 03/2019
Docetaxel	Hospira; Lot# DC21714A; Expiration 05/2019
Doxorubicin Hydrochloride	Actavis; Lot# 7LJ5121; Expiration 07/2019
Ellence	USP; Lot# F01341; Expiration 08/2018
Etoposide (Toposar)	Teva; Lot# 31321666B; Expiration 09/2019
Fludarabine	USP; Lot# H0K220; Expiration 11/2018
Fluorouracil	Accord; Lot# PT04863; Expiration 11/2018
Gemcitabine (Gemzar)	Hospira; Lot# GL31714A; Expiration 10/2018
Idarubicin	Teva; Lot# 31322658B; Expiration 02/2020
Ifosfamide	West Ward; Lot# BH0007; Expiation 11/2018
Irinotecan	LC Labs; Lot# RCN-105; Expiration 03/2024
Mechlorethamine HCl	Sigma Aldrich; Lot#MKBW4481V; Expiration 03/2019
Melphalan	USP; Lot# R068T0; Expiration 02/2019
Methotrexate	Hospira; Lot# E134437AA; Expiration 08/2019
Mitomycin C	Mylan; Lot# 7801652; Expiration 10/2019
Mitoxantrone	Sigma Aldrich; Lot# MKCD4771; Expiration 03/2019
Oxaliplatin	Cipla Ltd; Lot# GE70447; 07/2019
Paclitaxel (Taxol)	Hospira; Lot# D046865AA; Expiration 08/2018
Rituximab	Hetero; Lot# RB1711A; 12/2019
Thiotepa	Sigma; Lot# SLBV7203; Expiration 03/2019
Trisonex	Sigma Aldrich; Lot# BCBQ8570V; CAS# 1327-53-3
Vincristine Sulfate	Hospira; Lot# E047139AA; Expiration 04/2019
Vinorelbine	Actavis; Lot# 7B05012; Expiration 06/2019

COLLECTION MEDIA:

The collection media, which were selected, are listed in Table 2.

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Bleomycin, 15 mg/ml (15,000 ppm)	Distilled Water
Busulfan, 6 mg/ml (6,000 ppm)	Distilled Water
Carboplatin, 10 mg/ml (10,000 ppm)	Distilled Water
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	Distilled Water
Cytarabine, 100 mg/ml (100,000 ppm)	Distilled Water
Cytovene, 10 mg/ml (10,000 ppm)	Distilled Water
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Distilled Water
Daunorubicin, 5 mg/ml (5,000 ppm)	Distilled Water
Docetaxel, 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Distilled Water
Ellence, 2 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Distilled Water
Fludarabine, 25 mg/ml (25,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Gemcitabine (Gemzar), 38 mg/ml (38,000 ppm)	Distilled Water
Idarubicin, 1 mg/ml (1,000 ppm)	Distilled Water
Ifosfamide, 50.0 mg/ml (50,000 ppm)	Distilled Water
Irinotecan, 20.0 mg/ml (20,000 ppm)	Distilled Water
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	Distilled Water
Melphalan, 5 mg/ml (5,000 ppm)	Distilled Water
Methotrexate, 25 mg/ml, (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Mitoxantrone, 2.0mg/ml (2,000ppm)	Distilled Water
Oxaliplatin, 2.0 mg/ml (2,000 ppm)	Distilled Water
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Rituximab, 10 mg/ml (10,000 ppm)	Distilled Water
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Trisenox, 0.1 mg/ml (100 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Distilled Water
Vinorelbine, 10 mg/ml (10,000 ppm)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978
Deviation From Standard Test Method:	Used 1" Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	6-25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area

DETECTION METHOD OF CHEMICAL PERMEATION; UV/VIS ABSORPTION SPECTROMETRY:

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Bleomycin, 15 mg/ml (15,000 ppm)	290
Busulfan, 6 mg/ml (6,000 ppm)	197
Carboplatin, 10 mg/ml (10,000 ppm)	192
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	200
Cytarabine, 100 mg/ml (100,000 ppm)	272
Cytovene (Ganciclover), 10 mg/ml (10,000 ppm)	251
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	320
Daunorubicin, 5 mg/ml (5,000 ppm)	269
Docetaxel, 10.0 mg/ml (10,000 ppm)	231
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	232
Ellence, 2 mg/ml (2,000 ppm)	233 & 253
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	205
Fludarabine, 25 mg/ml (25,000 ppm)	261
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Gemcitabine (Gemzar), 38 mg/ml (38,000 ppm)	202
Idarubicin, 1 mg/ml (1,000 ppm)	257
Ifosfamide, 50.0 mg/ml (50,000 ppm)	200
Irinotecan, 20.0 mg/ml (20,000 ppm)	200
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	194
Melphalan, 5 mg/ml (5,000 ppm)	260
Methotrexate, 25 mg/ml, (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Mitoxantrone, 2.0mg/ml (2,000ppm)	242
Oxaliplatin, 2.0 mg/ml (2,000 ppm)	199
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	231
Rituximab, 10 mg/ml (10,000 ppm)	192
Thiotepa, 10.0 mg/ml (10,000 ppm)	199
Trisenox, 0.1 mg/ml (100 ppm)	191
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	220
Vinorelbine, 10 mg/ml (10,000 ppm)	212

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested specimens: Low Weight Powder Free Blue Nitrile Examination Gloves; Lot# 18030515A0501.

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Bleomycin	0.055	0.050	0.048	0.051
Busulfan	0.051	0.054	0.049	0.051
Carboplatin	0.050	0.056	0.051	0.052
Carmustine (BCNU)	0.054	0.052	0.052	0.053
Cisplatin	0.051	0.051	0.051	0.051
Cyclophosphamide	0.055	0.050	0.051	0.052
Cytarabine	0.052	0.051	0.053	0.052
Cytovene (Ganciclovir)	0.048	0.053	0.051	0.051
Dacarbazine (DTIC)	0.052	0.053	0.051	0.052
Daunorubicin	0.054	0.055	0.052	0.053
Docetaxel	0.051	0.051	0.054	0.052
Doxorubicin Hydrochloride	0.054	0.051	0.050	0.051
Ellence	0.050	0.051	0.051	0.051
Etoposide (Toposar)	0.053	0.049	0.048	0.050
Fludarabine	0.054	0.046	0.049	0.050
Fluorouracil	0.048	0.047	0.049	0.048
Gemcitabine (Gemzar)	0.055	0.052	0.051	0.053
Idarubicin	0.056	0.050	0.055	0.054
Ifosfamide	0.051	0.053	0.053	0.052
Irinotecan	0.054	0.052	0.056	0.054
Mechlorethamine HCl	0.048	0.047	0.054	0.049
Melphalan	0.053	0.053	0.055	0.054
Methotrexate	0.048	0.050	0.051	0.050
Mitomycin C	0.051	0.050	0.050	0.051
Mitoxantrone	0.049	0.046	0.054	0.050
Oxaliplatin	0.048	0.053	0.056	0.052
Paclitaxel (Taxol)	0.050	0.050	0.050	0.050
Rituximab	0.053	0.051	0.051	0.052
Thiotepa	0.050	0.051	0.058	0.053
Trisonex	0.050	0.046	0.057	0.051
Vincristine Sulfate	0.051	0.049	0.051	0.050
Vinorelbine	0.051	0.053	0.051	0.052
Weight/Unit Area (g/m2)	**47.4**			

RESULTS:

Table 5. Permeation Test Results on: Low Weight Powder Free Blue Nitrile Examination Gloves; Lot# 18030515A0501.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)	STEADY STATE PERM. RATE (Sample 1,2,3) (μg/cm²/minute)	OTHER OBSERVATIONS
Bleomycin, 15 mg/ml (15,000 ppm)	>240	N/A	Slight swelling and no degradation
Busulfan, 6 mg/ml (6,000 ppm)	>240	N/A	Slight swelling and no degradation
Carboplatin, 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	8.5 (12.7,13.4,8.5)	0.3 (0.3,0.3,0.3)	Moderate swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	>240	N/A	Slight swelling and no degradation
Cytarabine, 100 mg/ml (100,000 ppm)	>240	N/A	Slight swelling and no degradation
Cytovene, 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and discoloration
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and discoloration
Daunorubicin, 5 mg/ml (5,000 ppm)	>240	N/A	Slight swelling and no degradation
Docetaxel, 10.0 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Ellence, 2 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	>240	N/A	Moderate swelling and slight degradation
Fludarabine, 25 mg/ml (25,000 ppm)	>240	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240	N/A	Slight swelling and no degradation
Gemcitabine (Gemzar), 38 mg/ml (38,000 ppm)	>240	N/A	Slight swelling and no degradation

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)	STEADY STATE PERM. RATE (Sample 1,2,3) (µg/cm²/minute)	OTHER OBSERVATIONS
Idarubicin, 1 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Ifosfamide, 50.0 mg/ml (50,000 ppm)	>240	N/A	Slight swelling and no degradation
Irinotecan, 20.0 mg/ml (20,000 ppm)	>240	N/A	Moderate swelling and no degradation
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	>240	N/A	Slight swelling and no degradation
Melphalan, 5 mg/ml (5,000 ppm)	>240	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml, (25,000 ppm)	>240	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	>240	N/A	Slight swelling and no degradation
Mitoxantrone, 2.0mg/ml (2,000ppm)	>240	N/A	Slight swelling and no degradation
Oxaliplatin, 2.0 mg/ml (2,000 ppm)	>240	N/A	Slight swelling and no degradation
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	>240	N/A	Moderate swelling and slight degradation
Rituximab, 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation
Thiotepa, 10.0 mg/ml (10,000 ppm)	36.1 (51.2,36.1,45.6)	1.6 (2.1,1.5,1.2)	Slight swelling and no degradation
Trisenox, 0.1 mg/ml (100 ppm)	>240	N/A	Slight swelling and no degradation
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	>240	N/A	Slight swelling and no degradation
Vinorelbine, 10 mg/ml (10,000 ppm)	>240	N/A	Slight swelling and no degradation

Tiffany L. Heller
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Beijing, 102401 Cn

Re: K181130
Trade/Device Name: Powder Free Blue Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: July 16, 2018
Received: July 20, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181130

Device Name
Powder Free Blue Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
The Powder Free Blue Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.
The proposed device was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:
Chemotherapy Drug Permeation
The following chemicals have been tested with proposed device.

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Bleomycin	15 mg/ml (15,000 ppm)	>240
Busulfan	6 mg/ml (6,000 ppm)	>240
Carboplatin	10 mg/ml (10,000ppm)	>240
Carmustine (BCNU)	3.3 mg/ml (3,300ppm)	8.5 (12.7, 13.4, 8.5)
Cisplatin	1.0 mg/ml (1,000ppm)	>240
Cyclophosphamide(Cytoxan)	20.0 mg/ml (20,000ppm)	>240
Cytarabine	100 mg/ml (100,000ppm)	>240
Cytovene	10 mg/ml (10,000ppm)	>240
Dacarbazine(DTIC)	10.0 mg/ml (10,000ppm)	>240
Daunorubicin	5 mg/ml (5,000ppm)	>240
Docetaxel	10.0 mg/ml(10,000ppm)	>240
Doxorubicin Hydrochloride	2.0 mg/ml (2,000ppm)	>240
Ellence	2 mg/ml (2,000ppm)	>240
Etoposide(Toposar)	20.0 mg/ml(20,000ppm)	>240
Fludarabine	25 mg/ml(25,000ppm)	>240
Fluorouracil	50 mg/ml(50,000ppm)	>240
Gemcitabine (Gemzar)	38 mg/ml(38,000ppm)	>240
Idarubicin	1 mg/ml (1,000ppm)	>240
Ifosfamide	50.0 mg/ml (50,000ppm)	>240
Irinotecan	20.0 mg/ml (20,000ppm)	>240
Mechlorethamine HCI	1.0 mg/ml (1,000ppm)	>240
Melphalan	5 mg/ml (5,000ppm)	>240
Methotrexate	25mg/ml (25,000ppm)	>240
Mitomycin C	0.5 mg/ml (500 ppm)	>240
Mitoxantrone	2.0 mg/ml(2,000ppm)	>240
Oxaliplatin	2.0 mg/ml(2,000ppm)	>240
Paclitaxel (Taxol)	6.0 mg/ml(6,000ppm)	>240
Rituximab	10 mg/ml(10,000ppm)	>240
Thiotepa	10.0 mg/ml (10,000ppm)	36.1 (51.2, 36.1, 45.6)
Trisenox	0.1 mg/ml (100ppm)	>240
Vincristine Sulfate	1.0 mg/ml (1,000ppm)	>240
Vinorelbine	10 mg/ml(10,000ppm)	>240

*Please note that the following drugs have low permeation times:
Carmustine (BCNU): 8.5 minutes and Thiotepa: 36.1 minutes

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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510(k) Summary

This 510(k) Summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

The assigned 510(k) Number: K181130

1. Date of Preparation: 08/03/2018

2. Sponsor Identification

HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO., LTD.
EASTERN INDUSTRIAL ZONE, NANGONG CITY, HEBEI PROVINCE, CHINA

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Proposed Device Identification

Trade Name: Powder Free Blue Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs
Device Name: NITRILE Patient Examination Gloves (Powder Free)
Common Name: Patient Examination Gloves

Regulatory Information
Classification: I
Product Code: LZA, LZC
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

Indication for Use:
The Powder Free Blue Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.
The proposed device was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:
Chemotherapy Drug Permeation
The following chemicals have been tested with proposed device.

Chemotherapy Drug	Concentration	Breakthrough Minutes Detection Time in Minutes
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Cyclophosphamide(Cytoxan)	20.0 mg/ml (20,000ppm)	>240
Cytarabine	100 mg/ml (100,000ppm)	>240
Cytovene	10 mg/ml (10,000ppm)	>240
Dacarbazine(DTIC)	10.0 mg/ml (10,000ppm)	>240
Daunorubicin	5 mg/ml (5,000ppm)	>240
Docetaxel	10.0 mg/ml(10,000ppm)	>240
Doxorubicin Hydrochloride	2.0 mg/ml (2,000ppm)	>240
Ellence	2 mg/ml (2,000ppm)	>240
Etoposide(Toposar)	20.0 mg/ml(20,000ppm)	>240
Fludarabine	25 mg/ml(25,000ppm)	>240
Fluorouracil	50 mg/ml(50,000ppm)	>240
Gemcitabine (Gemzar)	38 mg/ml(38,000ppm)	>240
Idarubicin	1 mg/ml (1,000ppm)	>240
Ifosfamide	50.0 mg/ml (50,000ppm)	>240
Irinotecan	20.0 mg/ml (20,000ppm)	>240

Mechlorethamine HCI	1.0 mg/ml (1,000ppm)	>240
Melphalan	5 mg/ml (5,000ppm)	>240
Methotrexate	25mg/ml (25,000ppm)	>240
Mitomycin C	0.5 mg/ml (500 ppm)	>240
Mitoxantrone	2.0 mg/ml(2,000ppm)	>240
Oxaliplatin	2.0 mg/ml(2,000ppm)	>240
Paclitaxel (Taxol)	6.0 mg/ml(6,000ppm)	>240
Rituximab	10 mg/ml(10,000ppm)	>240
Thiotepa	10.0 mg/ml (10,000ppm)	36.1 (51.2,36.1, 45.6)
Trisenox	0.1 mg/ml (100ppm)	>240
Vincristine Sulfate	1.0 mg/ml (1,000ppm)	>240
Vinorelbine	10 mg/ml(10,000ppm)	>240

*Please note that the following drugs have low permeation times:
Carmustine (BCNU): 8.5 minutes and Thiotepa: 36.1 minutes

5. Predicate Device Identification

510(k) Number: K163146
Product Name: POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs
Manufacturer: HEBEI HONGSEN PLASTICS TECHNOLOGY CO., LTD.

6. Device Description

The proposed device, Powder Free Blue Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.
The proposed device is a Powder Free Nitrile Patient Examination Glove that is available in multiple sizes
The proposed device is provided non-sterile. The proposed device is made of Nitrile. The proposed device acts as a barrier.
The proposed device was tested according to the following standards: ASTM D6319-10, ASTM D5151-06, ASTM D6124-06, and ASTM D6978-05. These standards are identified in the following section "Non-clinical test conclusion.

7. Technological Comparison Tables

Table 1 General Comparison

Item	Proposed Device (K181130)	Predicate Device (K163146)	Remark
Product Code	LZA, LZC	LZA, LZC	SAME
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	SAME
Class	I	I	SAME
Intended use	The Powder Free Blue Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	The POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	SAME
Design Feature	ambidextrous	ambidextrous	SAME
Labeling Information	Single-use indication, powder free, device name, glove size and quantity, Nitrile Examination Gloves, Non-Sterile	Single-use indication, powder free, device name, glove size and quantity, Nitrile Examination Gloves, Non-Sterile	SAME
Chemotherapy Drug Permeation Claim	Bleomycin, Busulfan, Carboplatin, Carmustine (BCNU), Cisplatin, Cyclophosphamide(Cytoxan), Cytarabine, Cytovene, Dacarbazine(DTIC) , Daunorubicin, Docetaxel, Doxorubicin, Hydrochloride, Ellence, toposide(Toposar), Fludarabine, Fluorouracil, Gemcitabine (Gemzar), Idarubicin, Ifosfamide, Irinotecan, Mechlorethamine HCI, Melphalan, Methotrexate, Mitomycin C, Mitoxantrone, Oxaliplatin, Paclitaxel (Taxol), Rituximab, Thiotepa, Trisenox, Vincristine Sulfate, Vinorelbine	Fluorouracil, Etoposide (Toposar), Cyclophosphamid (Cytoxan), Carmustine (BCNU), Thiotepa, Paclitaxel (Taxol), Doxorubicin Hydrochloride, Dacarbazine (DTIC), Cisplatin, Carboplatin, Docetaxel, Ifosfamide, Irinotecan, Mechlorethamine HCL, Methotrexate, Mitomycin C, Mitoxantrone, Vincristine Sulfate	Different

Table 2 Device Dimensions Comparison

Proposed Device (K181130)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	230	230	230	min
	Width, mm	70	80	95	110	120	±10
	Thickness, mm:						
	Finger	0.07					±0.02
	Palm	0.05					min
	Cuff	0.05					±0.02
Predicate Device (K163146)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	230	230	230	min
	Width, mm	70	80	95	110	120	±10
	Thickness, mm:						
	Finger	0.10					±0.03
	Palm	0.08					±0.03
	Cuff	0.06					±0.03
Remark	Different						

Table 3 Performance Comparison

Item			Proposed Device (K181130)	Predicate Device (K163146)	Remark
Colorant			Blue	Blue	Similar
Physical properties	Before Aging	Tensile Strength	15 Mpa, min	15 Mpa, min	SAME
		Ultimate Elongation	500% min	500% min	
	After Aging	Tensile Strength	14 MPa, min	14 MPa, min	

		Ultimate Elongation	400% min	400% min	
	Comply with ASTM D6319			Comply with ASTM D6319	SAME
Detection of Holes			Not detected, in accordance with ASTM D5151	Not detected, in accordance with ASTM D5151	SAME
Powder Content			Max. 0.35 mg per glove	Max. 0.32 mg per glove	Different

Table 4 Safety Comparison

Item		Proposed Device (K181130)	Predicate Device (k163146)	Remark
Material		Nitrile	Nitrile	SAME
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Similar
	Sensitization	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	
	In Vitro Cytotoxicity	Under the conditions of the study, not cytotoxic	/	

Different Analysis:

1. The proposed device has different chemotherapy drug permeation claim to the predicate device.
The chemotherapy drug permeation results for the proposed device meets the specifications of ASTM D6978 except for Carmustine and Thiotepa.
2. The proposed device has different thickness specification to the predicate device, but all thickness of proposed devices meets the specifications of ASTM D 6319.
3. The proposed device has different powder content to the predicate device, but all powder content of proposed devices meets the specifications of ASTM D 6319.

8. Non-Clinical Test Conclusion

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

- ASTM D6319-10, Standard Specification for Nitrile Examination Gloves for Medical

Application.

- ASTM D5151-06 (Reapproved 2011), Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6124-06 (Reaffirmation 2011), Standard Test Method for Residual Powder on Medical Gloves.
- ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs
- ISO 2859-1:1999, "Sampling Procedures for Inspection by Attributes – Part I: Sampling Plans Indexed by Acceptable Quality Level (AQL) for Lot-by-Lot Inspection.
- ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Comparison Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.