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名　　称　河北泰能鸿森医疗科技有限公司

类　　型　其他有限责任公司

法定代表人　路文新

经营范围　丁腈手套、天然乳胶手套、新材料合成手套、无尘手套、PVC手套、医用外科手套、PE手套、PE套袖、PE围裙、一次性止血带、医用防护用品、劳保用品、医用耗材的研发、生产、销售；一次性医用防护口罩、医用外科口罩、普通医用口罩、民用口罩、床单、枕套、工作帽、无纺布制品的生产销售；消毒剂类、84消毒液、洗涤卫生用品、洗化卫生用品、消毒用品、清洁湿纸巾、消毒湿纸巾、卫生湿纸巾、测温枪、体温计、防护服、隔离服的生产、销售；医疗器械的生产、销售；防静电洁净服、帽、防静电无尘鞋、无尘擦拭布、手套的洗涤服务；新材料制品的研发，自营产品的进出口业务***(以上不含危险化学品及国家省市禁限制经营事项）（依法须经批准的项目，经相关部门批准后方可开展经营活动）

注册资本　肆亿伍仟陆佰贰拾万元整

成立日期　2012年09月07日

营业期限　2012年09月07日至 2032年09月06日

住　　所　南宫市东部工业聚集区

登记机关

2020 年 3 月 12 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

国家市场监督管理总局监制

CE Technical Documentation Review Report

Applicant:	**Hebei Titans Hongsen Medical Technology Co., Ltd.** Eastern Industrial Zone, Nangong City, Xingtai City, 051800 Hebei, China
Report Number:	**16804425.002**
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII
Product(s):	**Single-use Nitrile Patient Examination Gloves**
Type(s)/Model(s):	Powder- free (size：XS, S, M, L, XL)
Classification:	Class I (according to manufacturer's declaration)
Examination period:	Aug.22.2018
Date of expiry:	Jan.28.2020
Review result:	During the examination of the provided Technical Documentation (No.: HS20180410, Revision: A, dated 2018-04-12), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (China) Ltd.

Yuhong CHEN
Manager
Medical Services

Rev.01, 2002-10-10

Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing, 100022, P.R.China
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Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

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East 3rd Ring Road, Chaoyang Dist.
100022 BEIJING
CHINA

Contact

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

Date May 28, 2015

Application for : **EG-Baumusterbescheinigung PSA**
Certificate No. : BP 60101629 Sheet 0002
Device : Protective gloves
against chemicals acc. to EN 374/1:2003, EN 374/2:2014, EN 16523-1:2015
Type : TITANFINE REF HS6213, HS6214, HS6215, HS6216 & HS6217

Dear Ms. Liu,

Enclosed please find the above mentioned certificate. As agreed upon we kindly ask you to pass on the certificate to the licence holder:

The license holder is:

Hebei Hongsen Plastics
Eastern Industrial Accumulation Zon
CHI 051800 Nangong City, Hebei

Kind regards

Certification body

C. Albrecht

Dipl.-Ing. C. Albrecht

TÜV Rheinland
LGA Products GmbH

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Business Stream Products
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against chemicals acc. to EN 374/1:2003, EN 374/2:2014, EN 16523-1:2015
Type : TITANFINE REF HS6213, HS6214, HS6215, HS6216 & HS6217
Test requirement : see Certificate

Dear Mr. Lu,

A specimen of above mentioned product has been tested and found to be technically in compliance with § 20 and § 21 of the ProdSG (= German Product Safety Law).

The certificate is issued with the reservation that the licence holder applies all information required in § 6 of the ProdSG related to name of the manufacturer and, if need be, his authorized representative / the importer including their respective addresses on the product, its packing and/or the user's manual prior to marketing the product in the European Economic Area.

Enclosed please find the certificate of approval
No. BP 60101629 0002.

Kind regards

Certification body

C. Albrecht

Dipl.-Ing. C. Albrecht

Test sample: stored by warehouse Leipzig

TÜV Rheinland
LGA Products GmbH

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90431 Nürnberg

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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

EG-Baumusterbescheinigung
Richtlinie 89/686/EWG Artikel 10
zuletzt geändert durch Richtlinie 96/58/EWG
Persönliche Schutzausrüstungen

TÜVRheinland®

Registrier Nr.: BP 60101629 0002

Bericht Nr.: 21231212 002

Inhaber:
Hebei Hongsen Plastics
Technology Co., Ltd.
Eastern Industrial Accumulation Zone
051800 Nangong City, Hebei
China

Produkt:
Schutzhandschuhe
gegen Chemikalien gemäß EN 374/1:2003, EN 374/2:2014, EN 16523-1:2015

Identifikation:
TITANFINE REF HS6213, HS6214, HS6215, HS6216 & HS6217
Material: Nitril, blau, puderfrei
Größen: XS - XL

Ergänzung: Schutzhandschuhe entsprechen auch
EN 374-2:2014 und EN 16523-1:2015.

Die EG-Baumusterbescheinigung bezieht sich auf das o.g. Produkt. Es wird bescheinigt, dass das Produkt den grundlegenden Anforderungen nach Anhang II der Richtlinie 89/686/EWG 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 EG-Konformitätserklärung gemäß Anhang VI zu verwenden.

Gültig bis: 19.05.2020

Benannte Stelle

TÜV Rheinland LGA Products GmbH

Datum 28.05.2015

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 EG-Richtlinien angebracht werden. CE

C E R T I F I C A T E

EC Type-Examination Certificate
EEC Directive 89/686/EEC Article 10
as last amended by EEC Directive 96/58/EEC
Personal Protective Equipment

Registration No.: BP 60101629 0002

Report No.: 21231212 002

Holder:

Hebei Hongsen Plastics
Technology Co., Ltd.
Eastern Industrial Accumulation Zone
051800 Nangong City, Hebei
China

Product:

Protective gloves
against chemicals acc. to EN 374/1:2003, EN 374/2:2014, EN 16523-1:2015

Identification:

TITANFINE REF HS6213, HS6214, HS6215, HS6216 & HS6217
Material: nitrile, blue, powderfree
Size: XS - XL

Addition: Protective gloves also follow requirements of
EN 374-2:2014 und EN 16523-1:2015.

The EC 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 directive 89/686/EEC. 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 VI.

Valid till: 19.05.2020

Notified Body

Date 28.05.2015

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

Prüfbericht-Nr.: *Test Report No.:*	**21231212_001**	**Auftrags-Nr.:** *Order No.:*	3137466	Seite 1 von 15 *Page 1 of 15*
Kunden-Referenz-Nr.: *Client Reference No.:*	Ord. 1140017489	**Auftragsdatum:** *Order date:*	03.02.2015	
Auftraggeber: *Client:*	Hebei Hongsen Plastics Technology Co., Ltd. Eastern Industrial zone, Nangong City, Hebei, P.R. China			
Prüfgegenstand: *Test item:*	Schutzhandschuhe / Protective gloves			
Bezeichnung / Typ-Nr.: *Identification / Type No.:*	Nitrilhandschuhe (12 inch, blau) / nitrile gloves (12 inches, blue) TITANFINE REF HS6213, HS6214, HS6215, HS6216, HS6217			
Auftrags-Inhalt: *Order content:*	Baumusterprüfung / EC Type Approval			
Prüfgrundlage: *Test specification:*	EN 374-1:2003, EN 374-2:2003, EN 374-3:2003 Schutzhandschuhe gegen Chemikalien und Mikroorganismen *Protective gloves against chemicals and micro-organisms*			

Wareneingangsdatum: *Date of receipt:*	23.02.2015
Prüfmuster-Nr.: *Test sample No.:*	A*91054
Prüfzeitraum: *Testing period:*	27.02.2015 – 06.05.2015
Ort der Prüfung: *Place of testing:*	Prüfstelle für Textilien und PSA Leipzig
Prüflaboratorium: *Testing laboratory:*	TÜV Rheinland LGA Products GmbH
Prüfergebnis*: *Test result*:*	Pass

geprüft von / *tested by*:

07.05.2015	J. Voigt / Sachverständige/Expert	
Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

kontrolliert von / *reviewed by*:

07.05.2015	M. Schultz / Sachverständiger/Expert	
Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

Sonstiges / *Other*:

Zustand des Prüfgegenstandes bei Anlieferung: *Condition of the test item at delivery:* Prüfmuster vollständig und unbeschädigt *Test item complete and undamaged*

* Legende:	1 = sehr gut	2 = gut	3 = befriedigend	4 = ausreichend	5 = mangelhaft
	P(ass) = entspricht o.g. Prüfgrundlage(n)		F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	N/A = nicht anwendbar	N/T = nicht getestet
Legend:	*1 = very good*	*2 = good*	*3 = satisfactory*	*4 = sufficient*	*5 = poor*
	P(ass) = passed a.m. test specification(s)		*F(ail) = failed a.m. test specification(s)*	*N/A = not applicable*	*N/T = not tested*

V04

Liste der verwendeten Prüfmittel
List of used test equipment

Prüfmittel *Test equipment*	**Prüfmittel-Nr. / ID-Nr.** *Equipment No. / ID-No.*	**Nächste Kalibrierung** *Next calibration*
pH-Messgerät pH 340i	7440146	08/2015
pH meter pH 340i		
Stahllineal GOST 427-56	7440161	01/2016
steel ruler GOST 427-56		
Stifte für Fingerfertigkeit	7440197	11/2015
Pins for finger dexterity		
Martindale-Scheuerprüfgerät Martindale 103	7440134	09/2015
Martindale Abrasion Tester Martindale 103		
Handschuh Schnitt-Tester 3394/A Couptest	7440107	12/2015
Glove Cut-Tester 3394/A Couptest		
Universalprüfmaschine Inspekt Desk 10	7440191	03/2016
Multipurpose testing machine Inspekt Desk 10		
Universalprüfmaschine Inspekt Desk 20	7440192	03/2016
Multipurpose testing machine Inspekt Desk 20		
Luft-Leck-Prüfung	7440196	05/2016
Air leakage Tester		
Prüfgerät zur Penetration Wasser	7440193	05/2016
Tester for penetration of water		

Produktbeschreibung
Product description

1	**Produktdetails** *Product details*	5-Finger-Handschuh *5 finger gloves*
2	**Artikel / Modell** *Article / Model*	Nitrilhandschuhe (12 inch, blau) / *nitrile gloves (12 inches, blue)* TITANFINE REF HS6213, HS6214, HS6215, HS6216, HS6217
3	**Größe / Länge** *Size / Length*	XS, S, M, L, XL
4	**Leistungsstufen** *Performance levels*	chemisch/ *chemical* — mechanisch/ *mechanical*: (I) Ethyl acetate 0 — 1 0 0 1 (K) NaOH 40% 6 (L) H_2SO_4 96% 1
5	**Verwendete Materialien** *Used materials*	Nitril / *nitrile*
6	**Chargennr.** *Charge no.*	---
7	**Sonstiges** *Other*	Vorhersehbare Verwendung wurde betrachtet. Zurzeit liegen für das/die Produkt/e weder Schutzklauselverfahren an, noch ist ein erhöhtes Unfallaufkommen bekannt. *Foreseeable use was considered. Currently neither a safeguard clause procedure has been invoked nor is an increase in accidents known for this / these product (s).*
8	**Mitgeltende Dokumente / Prüfberichte** *Further aplicable documents / test reports*	Prüfbericht Permeation / *Test report permeation* Bericht-Nr. / *report nr.*: AZ196659 (17.03.2015)

Nitrile glove, 12 inches, blue, powder free

Absatz *Clause*	**EN 374-1:2003, EN 374-2:2003, EN 374-3:2003** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
	Der Originaltext wird nur auszugsweise wieder gegeben. Details sind dem Original-Dokument zu entnehmen. ***The original text is reproduced only in part. For details, be reffered to the original document.***		
EN 374-1	**Schutzhandschuhe gegen Chemikalien und Mikroorganismen** ***Protective gloves against chemicals and micro-organisms***		
1	**Anwendungsbereich** ***Scope***		
	EN 374 gilt in Verbindung mit EN 420 *EN 374 should be used in conjunction with EN 420*		
EN 420 4.1	Gestaltungsgrundsätze und Handschuhkonfektionierung — Allgemeines *Glove design and construction — General*		
	- bei normalen Tätigkeiten Schutz auf der höchstmöglichen Leistungsstufe - minimale Zeit zum An-/ Ausziehen - gesamte Leistung nicht wesentlich herabgesetzt durch Nähte *- in foreseeable conditions of use, protection at highest possible level* *- minimal time for put on/take off* *- overall not significantly decreased by seams*	gegeben *given*	P ☒ F ☐ N/A ☐ N/T ☐
EN 420 4.2	Widerstand des Handschuhmaterials gegen Wasserdurchdringung *Resistance of glove materials ti water penetration*		
	wenn gefordert, muss der Widerstand des Handschuhmaterials gegen Wasserdurchdringung nach folgenden Prüfvorschriften geprüft werden: - Lederhandschuhe nach EN 344-1 - Textile Erzeugnisse nach EN 20811 *if required, the gloves materials where resistance to water penetration have to tested according follow test methode:* *- leather gloves according to EN 344-1* *- textile products according to EN 20811*	---	P ☐ F ☐ N/A ☒ N/T ☐
EN 420 4.3	Unschädlichkeit von Schutzhandschuhen *Innocuousness of protective gloves*		
EN 420 4.3.1	Allgemeines *General*		
	- beim Gebrauch Schutz ohne gesundheitliche Schädigung - alle enthaltenen Substanzen, die bekannt sind, Allergien zu verursachen, sind anzugeben *- protection at use without harm to user* *- all substances contained which are known to cause allergies are named*	gegeben *given*	P ☒ F ☐ N/A ☐ N/T ☐

Absatz *Clause*	**EN 374-1:2003, EN 374-2:2003, EN 374-3:2003** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
	Azo-Farbstoffe *Azo dye stuff*		
	< 30 mg/kg nach / *according to*: 1907/2006/EU	---	P ☐ F ☐ N/A ☒ N/T ☐
EN 420 4.3.2	Bestimmung des pH-Wertes *Determination of pH-value*		
	Der pH-Wert für Handschuhe muss größer als 3,5 und kleiner als 9,5 sein. *The pH value for all gloves shall be greater than 3,5 and less than 9,5.*	pH-Wert / *pH- value* Innenhand / *Palm*: 6,8	P ☒ F ☐ N/A ☐ N/T ☐
EN 420 4.3.3	Bestimmung des Chrom(VI)-Gehaltes *Determination of chromium (VI) content*		
	Der Chrom(VI)-Gehalt von Handschuhen, die Leder enthalten, darf bei der Bestimmung nach dem Prüfverfahren nach EN ISO 17075:2007 3,0 mg/kg nicht überschreiten. Enthält der Handschuh verschiedene Arten von Leder, muss jede Leder Art, unabhängig davon, ob sie mit der Haut in Berührung kommt oder nicht, separat geprüft werden und die vorgenannte Anforderung erfüllen. *The quantity of Chromium VI in gloves containing leather shall not exceed 3,0 mg/kg when determined according to the test method described in EN ISO 17075:2007. If the glove includes different types of leather, whether in contact with the skin or not, each leather type shall be tested separately and comply with the above requirement.*	---	P ☐ F ☐ N/A ☒ N/T ☐
EN 420 4.3.4	Bestimmung des Protein Gehaltes *Determination of extractable protein content*		
	Schutzhandschuhe aus Naturkautschuk müssen hinsichtlich ihres extrahierbaren Proteingehalts die in EN 455-3 festgelegten Anforderungen erfüllen. Naturkautschuk: *Lowry- Prüfmethode* so gering wie vernünftigerweise praktikabel (ALARP) *Natural rubber gloves shall be submitted to requirements stated in EN 455-3 on extractable protein content.* *natural rubber: latex Lowry- test method* *as low as reasonably practicable (ALARP)*	---	P ☐ F ☐ N/A ☒ N/T ☐

Absatz *Clause*	**EN 374-1:2003, EN 374-2:2003, EN 374-3:2003** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
EN 420 4.4	Reinigung *Cleaning*		
	Sofern Pflegeanweisungen angegeben sind, sind die in den spezifischen Normen aufgeführten relevanten Prüfungen an den Handschuhen durchzuführen, bevor und nachdem sie der höchsten empfohlenen Anzahl von Reinigungen unterzogen worden sind. Die Leistungsstufen dürfen durch die empfohlene Anzahl der Reinigungen nicht negativ beeinflusst werden. *If care instructions are provided, the relevant tests of the specific standards shall be performed on the gloves, before and after they have been subjected to the maximum recommended number of cleaning cycles. The levels of performance shall not be negatively affected throughout the recommended number of cycles.*	---	P ☐ F ☐ N/A ☒ N/T ☐
EN 420 4.5	Elektrostatische Eigenschaften *Electrostatic properties*		
	wenn erforderlich/ *if required:* Das Prüfergebnis muss in den Herstellerinformationen angegeben werden zusammen mit den Informationen nach 7.3.11. Es dürfen keine Piktogramme für elektrostatische Eigenschaften verwendet werden. *The test result shall be reported in the information supplied by the manufacturer accompanied by the information stated in 7.3.11. Electrostatic pictograms shall not be used for this property.*	---	P ☐ F ☐ N/A ☒ N/T ☐
EN 420 5	**Komfort und Leistungsfähigkeit** ***Comfort and efficiency***		
EN 420 5.1	Größen *Sizing*		
EN 420 5.1.2	Größen und Maße der Handschuhe *Sizes and measurements of glove*		
Tab. 2, Tab. 3	(siehe Tabelle unten)	(siehe Tabelle unten)	P ☒ F ☐ N/A ☐ N/T ☐

Handschuhgröße *Glove size*	Handumfang *Hand circumference* [mm]	Handlänge *Hand length* [mm]	Mindestlänge des Handschuhs *Minimum length of glove* [mm]
6	152	160	220
7	178	171	230
8	203	182	240
9	229	192	250
10	254	204	260
11	279	215	270

Größe *Size*	Handschuhlänge *Glove length* [mm]
6	298
7	300
8	301
9	299
10	305
11	---

Absatz *Clause*	**EN 374-1:2003, EN 374-2:2003, EN 374-3:2003** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
EN 420 5.1.3	Handschuhe für besondere Anwendungen *Gloves for special applications*		
	für den speziellen Zweck passend (eindeutig angegeben in der Gebrauchanweisung) *fit for special purpose* *(clearly stated in instruction for use)*	---	P ☐ F ☐ N/A ☒ N/T ☐
EN 420 5.2	Beweglichkeit *Dexterity*		
Tab. 4	Leistungsstufe / *Performance level* / geringster Durchmesser des Stiftes / *smallest diameter of pin* [mm]: 1: 11 2: 9,5 3: 8 4: 6,5 5: 5	Prüfstift / *pin*: 5 mm	P ☒ F ☐ N/A ☐ N/T ☐ Stufe / *Level 5*
EN 420 5.3	Wasserdampfdurchlässigkeit (WDD) und Wasserdampfaufnahme (WDA) *Water vapour transmission (WVT) and Water vapour absorption (WVA)*		
EN 420 5.3.1	sofern durchführbar, müssen Schutzhandschuhe wasserdampfdurchlässig sein sofern gefordert: WDD ≥ 5 mg/ (cm²h) *protective gloves shall allow water vapour transmission.* *if required: WVT: ≥ 5 mg/ (cm².h)*	---	P ☐ F ☐ N/A ☒ N/T ☐
EN 420 5.3.2	wenn die Schutzstufe eine Wasserdampfdurchlässigkeit verhindert oder ausschließt, sollte dennoch der Effekt des Schwitzens so viel wie möglich reduziert sein falls gefordert: WDA: ≥ 8 mg/cm² für 8 h *where protection level inhibits or excludes water vapour transmission, effect of perspiration has to be reduced* *if required: WVA: ≥ 8 mg/cm² for 8 h*	---	P ☐ F ☐ N/A ☒ N/T ☐
2	**Normative Verweisungen** ***Normative references***		
3	**Begriffe** ***Terms and definition***		

Absatz	**EN 374-1:2003, EN 374-2:2003, EN 374-3:2003**	Messergebnisse - Bemerkungen	Bewertung
Clause	Anforderungen - Prüfungen / *Requirements - Tests*	*Measuring results - Remarks*	*Evaluation*

4 **Prüfverfahren**
Method of testing

Ausführliche Prüfverfahren werden in folgenden Teilen dieser Norm angegeben / *detailed test methods will be found in the following parts of this standard*:

Penetration EN 374-2 / *Penetration EN 374-2*
Permeation EN 374-3 / *Permeation EN 374-3*

5 **Anforderungen**
Performance requirements

5.1 **Kleinste flüssigkeitsundurchdringliche Länge**
Minimum liquid proof length

P ☐
F ☐
N/A ☒
N/T ☐

5.2 **Penetration**
penetration

5.2.1 Handschuhe müssen dicht sein bei der Prüfung nach den in den entsprechenden Abschnitten der EN 374-2 angegebenen Prüfverfahren und beide Prüfungen müssen bestanden werden nach den Kriterien in den entsprechenden Abschnitten der EN 374-2. Sollte eine Prüfung nicht durchführbar sein, muss der Grund angegeben werden.

Gloves shall not leak when tested according to the test methods in EN 374-2 (5.2 and 5.3) and both test shall be passed according to the criteria in the relevant clauses of EN 374-2. If one test proves unsuitable, the reason shall be reported.

5.2.2 Ein Handschuh wird als beständig gegen Mikroorganismen angesehen, wenn er mindestens der Stufe 2 bei der Prüfung gegen Penetration nach Anhang A der EN 374-2 entspricht.

A glove shall be considered as micro-organism resistant when it conforms to at least level 2 of the penetration test of annex A of EN 374-2.

Tab. A1

Leistungsstufe / *performance level*	Annehmbare Qualitätsrenzlage / *acceptable quality level unit*	Prüfniveau / *Inspection levels*
Niveau / *level* 3	< 0,65	G1
Niveau / *level* 2	< 1,5	G1
Niveau / *level* 1	< 4,0	S4

Luft-Leck-Prüfung / *Air leakage*

Wasser-Leck-Prüfung / *Water leakage*

geprüfte Menge/
tested quantity:
10 Stück/pieces
akzeptierte Fehler/
accepted defects:
0 Stück/pieces

Luft-Leck-Prüfung / *Air leakage*

	dicht/ not *leaking*	undicht/ *leaking*
	10	0

Wasser-Leck-Prüfung / *Water leakage*

	dicht/ not *leaking*	undicht/ *leaking*
	10	0

P ☒
F ☐
N/A ☐
N/T ☐

Absatz	**EN 374-1:2003, EN 374-2:2003, EN 374-3:2003**	Messergebnisse - Bemerkungen	Bewertung
Clause	Anforderungen - Prüfungen / *Requirements - Tests*	*Measuring results - Remarks*	*Evaluation*

5.3 **Permeation**
Permeation

5.3.1 Bezogen auf die Durchbruchzeit wird jede Kombination Schutzhandschuh/Prüfchemikalie in Klassen eingeteilt, die für jede einzelne Chemikalie gelten, bei der die Permeation durch den Handschuh verhindert wird (siehe Tabelle 1). – Prüfung gemäß EN 374-3

Each combination protective glove/test chemical is classified, in terms of breakthrough time, according to each individual chemical for which the glove resists permeation (see table 1). – testing in acc. to EN 374

5.3.2 Ein Handschuh wird als beständig gegen Chemikalien angesehen, wenn ein Schutzindex von mindestens Klasse 2 bei drei Prüfchemikalien nach Anhang A erhalten wird.

A glove shall have at least a permeation performance level 2 when tested against three chemicals taken from the list of test chemicals in annex A.

Anhang A/
Annex A

Kennbuchstabe *Code letter*	Prüfchemikalien *Chemical*
A	Methanol / *Methanol*
B	Aceton / *Acetone*
C	Acetonitril / *Acetonitrile*
D	Dichloromethan / *Dichloromethane*
E	Kohlenstoffdisulfid / *Carbon disulphide*
F	Toluol / *Toluene*
G	Diethylamin / *Diethylamine*
H	Tetrahydrofuran / *Tetrahydrofurane*
I	Ethylacetat / *Ethyl acetate*
J	n-Heptan / *n-Heptane*
K	Natriumhydroxid 40 % / *Sodium hydroxide 40 %*
L	Schwefelsäure 96 % / *Sulphuric acid 96 %*

Tab. 1

Durchbruchzeit / *Measured breakthroug time* [min]	Schutzindex / *Permeation perfomance level*
> 10	Klasse / *class* 1
> 30	Klasse / *class* 2
> 60	Klasse / *class* 3
> 120	Klasse / *class* 4
> 240	Klasse / *class* 5
> 480	Klasse / *class* 6

/*

Prüf-chemikalie / *Chemical*	Durchbruchzeit / *Measured breakthrough time* [min]	
Ethyl acetate	0	Level 0
NaOH 40%	>480	Level 6
H_2SO_4 96%	22	Level 1

Schutz gegen geringe chemische Risiken/
protection against low chemical risks

P ☒
F ☐
N/A ☐
N/T ☐

Absatz	EN 374-1:2003, EN 374-2:2003, EN 374-3:2003	Messergebnisse - Bemerkungen	Bewertung
Clause	Anforderungen - Prüfungen / *Requirements - Tests*	*Measuring results - Remarks*	*Evaluation*

5.4 **Mechanische Kennwerte**
Mechanical characteristics

Für jedes Handschuhmodell, das für den Einsatz zum Schutz gegen Chemikalien und/oder Mikroorganismen empfohlen wird, müssen Angaben zu folgenden mechanischen Prüfungen getroffen werden

For each glove style recommended for use against chemicals and/or micro-organisms the obtained performance level shall be reported in the instructions supplied by the manufacturer for the following mechanical tests:

Abriebfestigkeit / *Abrasion resistance*;
Schnittfestigkeit / *Blade cut resistance*;
Weiterreißfestigkeit / *Tearing resistance*;
Durchstichfestigkeit / *Puncture resistance*

nach den in EN 388 beschriebenen Prüfverfahren
according to the test methods described in EN 388.

EN 388 6.1 — Abriebfestigkeit / *Abrasion resistance*

Tab. 1

Leistungsstufe *Performance level*	Abriebfestigkeit [Zyklen] *Abrasion [cycles]*
1	100
2	500
3	2000
4	8000

Schleifpapier / *abrasive paper*:
Klingspor PL31B Gritt 180

Durchbruch bei ca. [Zyklen]
Breaktrough at about [cycles]

1. Lage / *layer*	2. Lage / *layer*
100-500	---
500-2000	---
500-2000	---
500-2000	---

niedrigster Wert zur Klassifizierung / *lowest value for classification:* *100*

P ☒ F ☐ N/A ☐ N/T ☐

Stufe / *level 1*

EN 388 6.2 — Schnittfestigkeit / *Blade cut resistance*

Tab. 1

Leistungsstufe *Performance level*	Schnittfestigkeit [Faktor] *Blade cut resistance [Factor]*
1	1,2
2	2,5
3	5,0
4	10,0
5	20,0

Index i:	1,1	1,1
	1,1	1,1
	1,1	1,1
	1,1	1,1
	1,1	1,1
Index I:	1,1	1,1

niedrigster Index I zur Klassifizierung / *lowest Index I for classification:* 1,1

P ☐ F ☐ N/A ☒ N/T ☐

Stufe / *level 0*

Absatz *Clause*	**EN 374-1:2003, EN 374-2:2003, EN 374-3:2003** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*

EN 388 6.3 — Weiterreißfestigkeit / *Tear resistance*

Tab. 1

Leistungsstufe *Performance level*	Weiterreißfestigkeit [N] *Tear resistance [N]*
1	10
2	25
3	50
4	75

Einzelwerte [N]
Several values [N]

1. Lage / *layer*	2. Lage / *layer*
1,78	---
1,97	---
1,92	---
1,67	---

niedrigster Wert zur Klassifizierung / *lowest value for classification:* *1,67 N*

Bewertung: P ☐ F ☐ N/A ☒ N/T ☐

Stufe / *level 0*

EN 388 6.4 — Durchstichfestigkeit / *Puncture resistance*

Tab. 1

Leistungsstufe *Performance level*	Durchstichfestigkeit [N] *Puncture resistance [N]*
1	20
2	60
3	100
4	150

Einzelwerte [N]
several values [N]
21,22 27,88
26,88 26,20

niedrigster Wert zur Klassifizierung / *lowest value for classification:* *21,22 N*

Bewertung: P ☒ F ☐ N/A ☐ N/T ☐

Stufe / *level 1*

6 **Kennzeichnung**
Marking

Die Kennzeichnung von Schutzhandschuhen muss in Übereinstimmung mit dem entsprechenden Abschnitt in EN 420 erfolgen, sowie dem entsprechenden Piktogramm und der Nummer der EN 374.

The marking of protective gloves shall be in accordance with the relevant clause in EN 420. The appropriate pictogram shall be used together with number of EN 374.

EN 420 7.1 — Kennzeichnung und Information – Allgemeines / *Marking and Information – General*

Alle Angaben müssen präzise und umfassend sein und mindestens in der offizielle Sprache des Bestimmungslandes.

All details have to be precise and in official language of country of destination.

gegeben

given

Bewertung: P ☒ F ☐ N/A ☐ N/T ☐

Absatz *Clause*	**EN 374-1:2003, EN 374-2:2003, EN 374-3:2003** Anforderungen - Prüfungen / *Requirements - Tests*	Messergebnisse - Bemerkungen *Measuring results - Remarks*	Bewertung *Evaluation*
EN 420 7.2	Kennzeichnung und Information – Kennzeichnung *Marking and Information – Marking*		
EN 420 7.2.1	Jeder Schutzhandschuh muss mit folgenden Angaben gekennzeichnet sein: - Name, Handelsmarke oder andere Erkennungs-merkmale des Herstellers oder seines Repräsentanten - Handschuhbezeichnung (Handelsname oder Code, der dem Anwender die eindeutige Identifizierung des Produkts innerhalb des Sortiments des Herstellers oder bevollmächtigten Repräsentanten erlaubt) - Größenbezeichnung - Kennzeichnung mit Verfallsdatum - das Piktogramm mit der Nummer der Norm und die Leistungsstufen *Each protective glove shall be marked with the following information:* *- Name, trade mark or other means of identification of manufacturer or his authorized representative* *- Glove designation (commercial name or code allowing the user to identify clearly the product within the manufacturer's/authorized representative's range)* *- Size designation* *- Marking with date of obsolescence* *- Pictogram with number of standard and performance levels*	Diese Information befindet sich auf Verpackung Hebei Hongsen Plastics Technology Co., Ltd. Titanfine REF HS6213, HS6214, HS6215, HS6216, HS6217 z.B. M Platzhalter gegeben gegeben *This information is available on the packing* *Hebei Hongsen Plastics Technology Co., Ltd.* *Titanfine REF HS6213, HS6214, HS6215, HS6216, HS6217* *e.g. M* *placeholder given* *given*	P ☒ F ☐ N/A ☐ N/T ☐
	für Schutzhandschuhe, die die Anforderungen an Penetration und Permeation erfüllen – Piktogramm für chemische Gefahren *for gloves complying to the requirements for penetration and permeation – chemical pictogram*:  ADF	---	P ☐ F ☐ N/A ☒ N/T ☐
	oder/*or* für Schutzhandschuhe, die nur die Anforderungen an die Penetration erfüllen – Piktogramm für wasserfeste Schutzhandschuhe und geringen Schutz gegen chemische Gefahren / *for gloves complying tot he requirement for penetration – pictrogram for waterproof gloves with low chemical protection* 	gegeben *given*	P ☒ F ☐ N/A ☐ N/T ☐

Absatz	**EN 374-1:2003, EN 374-2:2003, EN 374-3:2003**	Messergebnisse - Bemerkungen	Bewertung
Clause	Anforderungen - Prüfungen / *Requirements - Tests*	*Measuring results - Remarks*	*Evaluation*
EN 420 7.2.2	Kennzeichnung und Information – Kennzeichnung der Verpackung *Marking and Information – Marking of Packaging*		
	Jede kleinste Verpackungseinheit, welche den Handschuh unmittelbar enthält, muss eindeutig mit den nachfolgenden Angaben gekennzeichnet sein:		P ☒ F ☐ N/A ☐ N/T ☐
	- Name und volle Anschrift des Herstellers oder seines autorisierten Repräsentanten	Hebei Hongsen Plastics Technology Co., Ltd.	
	- Handschuhbezeichnung (Handelsname oder Code, der dem Anwender die eindeutige Identifizierung des Produkts innerhalb des Sortiments des Herstellers oder bevollmächtigten Repräsentanten erlaubt)	Titanfine REF HS6213, HS6214, HS6215, HS6216, HS6217	
	- Größenbezeichnung	z.B. M	
	- Kennzeichnung mit Verfallsdatum	Platzhalter gegeben	
	- Hinweis, wo die Information des Herstellers zu erhalten ist	gegeben	
	- bei einfachen Handschuhen der Hinweis, „Nur bei minimalen Gefahren“ o. ä.	N/A	
	- das Piktogramm mit der Nummer der Norm und die Leistungsstufen	gegeben	
	- CE-Zeichen gemäß Richtlinie 89/686/EWG	gegeben	
	Each packaging enclosure that immediately contains the gloves shall be clearly marked with the following:		
	- Name, trade mark or other means of identification of manufacturer or his authorized representative	*Hebei Hongsen Plastics Technology Co., Ltd.*	
	- Glove designation (commercial name or code allowing the user to identify clearly the product within the manufacturer's/authorized representative's range)	*Titanfine REF HS6213, HS6214, HS6215, HS6216, HS6217*	
	- Size designation	*e.g. M*	
	- Marking with date of obsolescence	*placeholder given*	
	- Note where the information of the manufacturer is to obtain	*gegeben*	
	- for simle gloves note “Only for minimal risks” etc.	*N/A*	
	- Pictogram with number of standard and performance levels	*given*	
	- CE-mark in accordance to Directive 89/686/EEC	*given*	

Absatz	**EN 374-1:2003, EN 374-2:2003, EN 374-3:2003**	Messergebnisse - Bemerkungen	Bewertung
Clause	Anforderungen - Prüfungen / *Requirements - Tests*	*Measuring results - Remarks*	*Evaluation*

7	**Information des Herstellers** ***Information supplied by the manufacturer***		
	Informationen des Herstellers müssen den Anforderungen in EN 420 entsprechen. *The information supplied by the manufacturer shall be in accordance with the requirements for information as defined in EN 420.*		
EN 420 7.3	Folgende Mindestinformationen müssen beigefügt werden: - Name und volle Anschrift des Herstellers oder seines autorisierten Repräsentanten - Artikelbezeichnung, Code oder Nr. - Informationen über verfügbare Größen - EN 374: 2003 und/ oder EN 388:2003, mit Piktogramm und Leistungsstufen - falls erforderlich, Verfallsdatum - Informationen, wenn der Schutz nur für Teile der PSA gewährleistet ist - mögliche Probleme - Gebrauchsanweisung, auch beim Gebrauch mit anderen PSA - Pflegekennzeichnung *The following minimum information shall be supplied:* *- Name and full address of manufacturer or his authorized representative* *- Glove designation* *- Information on available size range* *- Reference to EN 374:2003 or/ and EN 388:2003 pictogram with performance levels* *- if the expected shelf-life of the gloves is reduced by aging, the expiration date have to be added* *- if protection is only given, for part of gloves, information have to be added* *- possible problems* *- instruction for use for gloves and also for use with combination of other PPE* *- care label*	 Hebei Hongsen Plastics Technology Co., Ltd. Titanfine REF HS6213, HS6214, HS6215, HS6216, HS6217 gegeben gegeben gegeben N/A gegeben N/A N/A *Hebei Hongsen Plastics Technology Co., Ltd.* *Titanfine REF HS6213, HS6214, HS6215, HS6216, HS6217* *given* *given* *given* *N/A* *given* *N/A* *N/A*	P ☒ F ☐ N/A ☐ N/T ☐

Absatz	**EN 374-1:2003, EN 374-2:2003, EN 374-3:2003**	Messergebnisse - Bemerkungen	Bewertung
Clause	Anforderungen - Prüfungen / *Requirements - Tests*	*Measuring results - Remarks*	*Evaluation*
	Zusatzinformationen:		P ☒ F ☐ N/A ☐ N/T ☐
	- Einzelheiten zu besonderen Prüfungen, die unter anderen klimatischen Bedingungen durchgeführt wurden, müssen angegeben werden	N/A	
	- falls zutreffend muss darauf hingewiesen werden, dass die Gesamtklassifizierung bei Handschuhen mit zwei oder mehreren nicht miteinander verbundenen Lagen nicht notwendigerweise die Leistungsfähigkeit der äußersten Lage wiedergibt	N/A	
	- Ein Warnhinweis muss enthalten sein, dass in Fällen, bei denen ein Risiko besteht, sich in bewegten Maschinenteilen zu verfangen, keine Handschuhe getragen werden sollten	gegeben	
	- Es muss eine Aufstellung über die geprüften Chemikalien und den entsprechenden Schutzindex für die geprüften Chemikalien und den entsprechenden Schutzindex für die Permeationsprüfung enthalten sein. Ist diese Liste nur ein Teil der verfügbaren Information, so muss dies deutlich hervorgehoben und ein Verweis auf weitere Informationsquellen gemacht werden, z. B. Broschüren, Telefon- oder Faxnummern oder Internetseiten usw.	gegeben	
	- Die Informationen müssen einen Warnhinweis enthalten, dass durch die Angabe des Schutzindexes keine Aussage gemacht wird über die tatsächliche Schutzdauer am Arbeitsplatz, da weitere Faktoren wie Temperatur, Abrieb usw. die Gebrauchstauglichkeit beeinflussen.	gegeben	
	- Die Leistungsstufe und die annehmbare Qualitätsgrenzlage (AQL) für die Prüfung der Penetration in der Produktion sind anzugeben.	N/A	
	Additional information:		
	- details of any special tests carried out in a different environment shall be given	*N/A*	
	- if relevant, note that for gloves with two or more non-bonded layers overall classification does not necessarily reflect the performance of the outermost layer	*N/A*	
	- users should be warned that gloves should not be worn when there is a risk of entanglement by moving parts of machines	*given*	
	- shall include the list of chemicals to which the gloves have been tested and the performance levels obtained in permeation testing. If this list represents only a section of the available information, then this shall be clearly stated and the reference to where additional information can be obtained shall be mentioned, e.g. separate brochure, telephone or fax no., website etc.	*given*	
	- Besides the information provided, a warning shall be added that this information does not reflect the actual duration of protection in the workplace due to other factors influencing the performance, such as temperature, abrasion, degradation etc.	*given*	
	- The level of performance and associated AQL for penetration production control shall be reported.	*N/A*	

2013-2014

CERTIFICATE OF REGISTRATION

This Certifies that:

HEBEI HONGSEN PLASTICS TECHNOLOGY CO., LTD
Eastern industrial accumulation area, , Nangong
Xingtai , Hebei , 051800 , CHINA

Was registered with US Food & Drug Administration, Center for Devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807, by Manton Business and Technology Services.

Owner Operator Number: 10045284

Listing Number	Product Code(s)	510k Number	Device Name
D204349	LZA	K131440	Polymer patient examination glove

Date of verification: 2013-11-05

This Certificate affirms that Manton Business and Technology Services has verified that the above stated facility is registered with the US Food & Drug Administration, Center for Drug Evaluation and Research, Office of Drug Registration and Listing pursuit to the Code of Federal Regulations 21 CFR 207, on the date stated above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. Manton Business and Technology Services assume no liability to any person or entity in connection with the foregoing. Manton Business and Technology Services is a private registration agent and is not affiliated with the US Food and Drug Administration.

Manton Business and Technology Services
New Jersey, USA

Chengyu Shen
Director
11-05-2013

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, Hebei Province 051800, P. R. China
Operation Address: Dongjin Sreet, Eastern Industrial Accumulation Zone, Nangong City, Hebei Province 051800, 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 2019-02-14 until 2021-04-08.
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

2019-02-14

TÜV Rheinland Cert GmbH
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www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

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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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date 2018-06-27

X. Ren

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 25, 2013

Hebei HongSen Plastics Technology Company Limited
C/O Charles Shen
Manton Business and Technology Services
5 Carey Street
PENNINGTON NJ 08534 US

Re: K131440
Trade/Device Name: Powder Free Nitrile Patient Examination Gloves, Blue Color (Brand Name Titans)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: July 11, 2013
Received: July 1, 2013

Dear Mr. Shen:

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

for

Kwame Ulmer M.S.
Acting Division 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131440

Device Name
Powder Free Nitrile Patient Examination Gloves, Blue color (Brand Name: Titans)

Indications for Use *(Describe)*

The Titan powder free nitrile patient examination glove, blue color, is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. It has blue color and is sold as non sterile.

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

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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Elizabeth F. Claverie
2013.09.25 14:04:24 -04'00'

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 18, 2015

HEBEI HONGSEN PLASTICS TECHNOLOGY CO., LTD
C/O Mr. Ray Wang
Beijing Believe Tech. Service Co., LTD
1-202, Build 3, Beijing New World, No. 5 Chaoyang Rd.
Chaoyang District, Beijing, 100024
China

Re: K150340
Trade/Device Name: POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: NITRILE Patient Examination Gloves (Power Free)
Regulatory Class: I
Product Code: LZA
Dated: May 14, 2015
Received: May 18, 2015

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division 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 & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Hebei Titans Medical Supply Technology Group.,ltd.
% Ray Wang
Official Correspondent
Beijing Believe Tech. Service Co., Ltd.
5-1206, Build 332, Dafangju, No.25 Banbidian Rd., Li Yuan, Tongzhou District
Beijing, BeiJing 101121 CN

Re: K163553
Trade/Device Name: Powder Free Nitrile Patient Examination Gloves, Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: April 27, 2017
Received: May 1, 2017

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. 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.

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the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163553

Device Name
Powder Free Nitrile Patient Examination Gloves, Blue

Indications for Use *(Describe)*
The powder free nitrile patient examination glove 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

The assigned 510(k) Number: K163553

1. Date of Preparation: 2017/05/16

2. Sponsor

HEBEI TITANS MEDICAL SUPPLY TECHNOLOGY GROUP CO., LTD.
EAST OF JINGQIANG COMMUNITY, DAQING STREET, NANGONG, XINGTAI, HEBEI PROVINCE, CHINA

Contact Person: Mr. ShaoZhang Nan
Tel: +86-0319-7295820
Fax: +86-0319-7295801
Email: nanshaozhang@163.com

3. Submission Correspondent

Mr. Ray Wang
Beijing Believe Tech. Service Co., Ltd.
Email: Ray.Wang@believe-med.com

4. Proposed Device Identification

Trade Name: Powder Free Nitrile Patient Examination Gloves, Blue
Device Name: NITRILE Patient Examination Gloves (Powder Free)
Common Name: Patient Examination Gloves

Classification: I
Product Code: LZA
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

Indication for Use Statement:
The powder free nitrile patient examination glove 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: K131440
Product Name: Powder free Patient Examination Gloves, Blue Color
Manufacturer: Hebei HongSen Plastics Technology Co., Ltd.

6. Device Description

The proposed device, Powder Free Nitrile Patient Examination Gloves 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 Powder Free Nitrile Patient Examination Gloves, and includes variations of different size and color. The colors of proposed device is Blue.

The proposed device is not provided as sterilized
The proposed device is made of Nitrile.

7. Non-Clinical Test Conclusion

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

ASTM D6319-10 (Reapproved 2015), Standard Specification for Nitrile Examination Gloves for Medical Application.
ASTM D 5151-06 (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.
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.

8. Substantially Equivalent Comparison Conclusion

Table III-1 General Comparison

ITEM	Proposed Device Powder Free Nitrile Patient Examination Gloves, Blue	Predicate Device (k131440) Powder free Patient Examination Gloves, Blue Color	Remark
Product Code	LZA	LZA	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indication for Use	The powder free nitrile patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Titan powder free nitrile patient examination glove, blue color, is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner. It has blue color and is sold as non-sterile.	Same
Powdered or Powered free	Powdered free	Powdered free	Same
Design Feature	ambidextrous, smooth	ambidextrous, smooth	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

Table III-2 Device Dimensions Comparison

Proposed Device Powder Free Nitrile Patient Examination Gloves, Blue	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
Predicate Device (k131440) Powder free Patient Examination Gloves, Blue Color	Designation	Size						Tolerance
		XS	S	M	L	XL	XXL	
Remark	Different 1							

Different 1 analysis:

The proposed device has different size specification to the predicate device, and all specific size specifications for the predicate are not available for comparison, but the predicate and proposed device both meet the specifications of ASTM D 6319.

Table III-3 Performance Comparison

ITEM			Proposed Device Powder Free Nitrile Patient Examination Gloves, Blue	Predicate Device (k131440) Powder free Patient Examination Gloves, Blue Color	Remark
Colorant			Blue	Blue	Same
Physical Properties	Before Aging	Tensile Strength	15 MPa,	Comply with ASTM D6319	Same
		Ultimate Elongation	500 % min	Comply with ASTM D6319	Same
	After Aging	Tensile Strength	14 MPa	Comply with ASTM D6319	Same
		Ultimate Elongation	400 % min	Comply with ASTM D6319	Same
	Comply with ASTM D6319			Comply with ASTM D6319	Same
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151	Be free from holes when tested in accordance with ASTM D5151	Same
Powder Content			Max. 0.32 mg per glove	Meet the requirements of ASTM 6319	Same

Table III-4Safety Comparison

ITEM		Proposed Device Powder Free Nitrile Patient Examination Gloves, Blue	Predicate Device (k131440) Powder free Patient Examination Gloves, Blue Color	Remark
Material		Nitrile	Nitrile	Same
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	Same
	Sensitization	Under conditions of the study, not a sensitizer.		
Label and Labeling		Meets recommendations as outlined in the Glove Guidance Manual.	Meets recommendations as outlined in the Glove Guidance Manual.	Same

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.

Hebei Titans Hongsen Medical Technology Co., LTD.
% Ray Wang
General Manager
Beijing Believe-Med Technology Services Co., Ltd.
Rm. 912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District
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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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

Contact Person: Mr. ShaoZhang Nan
Tel: +86-0319-7295820
Fax: +86-0319-7295801
Email: nanshaozhang@163.com

3. Designated Submission Correspondent

Mr. Ray Wang

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: 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.

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Cytarabine	100 mg/ml (100,000ppm)	>240
Cytovene	10 mg/ml (10,000ppm)	>240
Dacarbazine(DTIC)	10.0 mg/ml (10,000ppm)	>240
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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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 13, 2017

Hebei Hongsen Plastics Technology Co, Ltd
% Ray Wang
Official Correspondent
Beijing Believe Tech. Service Co., Ltd.
5-1206, Build 332, Dafangju, No.25 Banbidian Rd.,liyuan,
Tongzhou District
Beijing, 101121 CN

Re: K163146
Trade/Device Name: POWDER FREE Blue Nitrile 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: January 3, 2017
Received: January 9, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely,

Michael J. Ryan -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163146

Device Name
POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
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.
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
Fluorouracil	50.0 mg/ml (50,000 ppm)	> 240
Etoposide (Toposar)	20.0 mg/ml (20,000 ppm)	> 240
Cyclophosphamid (Cytoxan)	20.0 mg/ml (20,000 ppm)	> 240
*Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	45.0
*Thiotepa	10.0 mg/ml (10,000 ppm)	30.0
Paclitaxel (Taxol)	6.0 mg/ml (6,000 ppm)	> 240
Doxorubicin Hydrochloride	2.0 mg/ml (2,000 ppm)	> 240
Dacarbazine (DTIC)	10.0 mg/ml (10,000 ppm)	> 240
Cisplatin	1.0 mg/ml (1,000 ppm)	> 240
Carboplatin	10.0 mg/ml (10,000 ppm)	> 240
Docetaxel	10.0 mg/ml (10,000 ppm)	> 240
Ifosfamide	50.0 mg/ml (50,000 ppm)	> 240
Irinotecan	20.0 mg/ml (20,000 ppm)	> 240
Mechlorethamine HCL	1.0 mg/ml (1,000 ppm)	> 240
Methotrexate	25.0 mg/ml (25,000 ppm)	> 240
Mitomycin C	0.5 mg/ml (500 ppm)	> 240
Mitoxantrone	2.0 mg/ml (2,000 ppm)	> 240
Vincristine Sulfate	1.0 mg/ml (1,000 ppm)	> 240

* Please note that the following drugs have low permeation times:
Carmustine (BCNU): 45 minutes and Thiotepa: 30 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) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K163146

1. Date of Preparation: 02/08/2017

2. Sponsor Identification

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

Contact Person: Mr. ShaoZhang Nan
Tel: +86-0319-7295820
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3. Designated Submission Correspondent

Mr. Ray Wang

Beijing Believe Technology Service Co., Ltd.
5-1206, Build 332, DaFangJu, No.25 BanBiDian Rd.,
LiYuan Town, TongZhou District, Beijing, 101121, China

Tel: +86-21-59120817
Fax: +86-21-59120817
Email: Ray.Wang@believe-med.com

4. Proposed Device Identification

Trade Name: POWDER FREE Blue Nitrile 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 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
Fluorouracil	50.0 mg/ml (50,000 ppm)	> 240
Etoposide (Toposar)	20.0 mg/ml (20,000 ppm)	> 240
Cyclophosphamid (Cytoxan)	20.0 mg/ml (20,000 ppm)	> 240
*Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	45.0
*Thiotepa	10.0 mg/ml (10,000 ppm)	30.0
Paclitaxel (Taxol)	6.0 mg/ml (6,000 ppm)	> 240
Doxorubicin Hydrochloride	2.0 mg/ml (2,000 ppm)	> 240
Dacarbazine (DTIC)	10.0 mg/ml (10,000 ppm)	> 240
Cisplatin	1.0 mg/ml (1,000 ppm)	> 240
Carboplatin	10.0 mg/ml (10,000 ppm)	> 240
Docetaxel	10.0 mg/ml (10,000 ppm)	> 240
Ifosfamide	50.0 mg/ml (50,000 ppm)	> 240
Irinotecan	20.0 mg/ml (20,000 ppm)	> 240
Mechlorethamine HCL	1.0 mg/ml (1,000 ppm)	> 240
Methotrexate	25.0 mg/ml (25,000 ppm)	> 240
Mitomycin C	0.5 mg/ml (500 ppm)	> 240
Mitoxantrone	2.0 mg/ml (2,000 ppm)	> 240
Vincristine Sulfate	1.0 mg/ml (1,000 ppm)	> 240

*Please note that the following drugs have low permeation times:
Carmustine (BCNU): 45 minutes and Thiotepa: 30 minutes

5. Predicate Device Identification

510(k) Number: K141982
Product Name: Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile, Tested for use with Chemotherapy Drugs
Manufacturer: WRP Asia Pacific Sdn Bhd.

6. Device Description

The proposed device, 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.
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. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all specifications and the proposed device is Substantially Equivalent (SE) to the predicate device. 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.

8. Substantially Equivalent (SE) Comparison Conclusion

Table 1 General Comparison

Item	Proposed Device POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs (K163146)	Predicate Device Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Tested for Use with Chemotherapy Drugs (K141982)	Remark
Product Code	LZA, LZC	LZA, LZC	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indication for use	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.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Powdered or Powered free	Powdered free	Powdered free	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	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	Fluorouracil, Etoposide (Toposar), Cyclophosphamid (Cytoxan), Carmustine (BCNU), Thiotepa, Paclitaxel (Taxol), Doxorubicin Hydrochloride, Dacarbazine (DTIC), Cisplatin, Ifosfamide, Mitoxantrone, Vincristine Sulfate	Analysis 1

Analysis 1:

The proposed and predicate devices both have a tested for use with chemotherapy drugs claim. However, different chemotherapy drugs have been tested for the proposed device and the results meet the specifications of ASTM D6978

Table 2 Device Dimensions Comparison

Proposed Device POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs (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
Predicate Device Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Tested for Use with Chemotherapy Drugs (K141982)	Size: Min. 240 mm Thickness: Finger (0.07-0.10); Palm(0.07-0.09); Cuff (0.06-0.08)						
Remark	Analysis 2						

Analysis 2:

The proposed device has different size specification as compared to the predicate device, but the proposed device meets the specifications of ASTM D6319.

Table 3 Performance Comparison

Item			Proposed Device POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs (K163146)	Predicate Device Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Tested for Use with Chemotherapy Drugs (K141982)	Remark
Colorant			Blue	Blue	Same
Physical properties	Before Aging	Tensile Strength	15 Mpa, min	Meet the Requirements of ASTM D 6319	Analysis 3
		Ultimate Elongation	500% min	Meet the Requirements of ASTM D 6319	
	After Aging	Tensile Strength	14 MPa, min	Meet the Requirements of ASTM D 6319	
		Ultimate Elongation	400% min	Meet the Requirements of ASTM D 6319	
	Comply with ASTM D6319			Comply with ASTM D6319 14 MPa. Min/500% min. before aging; 14 MPa. Min./400% min. After aging	Same
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151 AQL 1.5	Be free from holes when tested in accordance with ASTM D5151 under AQL 2.5/Inspection Level G-I	Same
Powder Content			Max. 0.32 mg per glove	Meet the requirements of ASTM D6319 Less than 2mg per glove	Same

Analysis 3:

The proposed device has a different Ultimate Elongation after aging as compared to the predicate device, but the proposed device meets the specifications of ASTM D6319.

Table 4 Safety Comparison

Item		Proposed Device POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs (K163146)	Predicate Device Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Tested for Use with Chemotherapy Drugs (K141982)	Remark
Material		Nitrile	Nitrile	Same
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	Same
	Sensitization	Under the conditions of the study, not a sensitizer		
Label and Labeling		Meet FDA's Recommendations	Meet FDA's Recommendations	Same

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device, POWDER FREE Blue Nitrile GLOVES, Tested for Use with Chemotherapy Drugs, is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Tested for Use with Chemotherapy Drugs.

对外贸易经营者备案登记表

备案登记表编号：01253598　　进出口企业代码：1300054013624

经营者中文名称	河北鸿森塑胶科技有限公司		
经营者英文名称	HEBEI HONGSEN PLASTICS TECHNOLOGY CO.,LTD		
组织机构代码	054013624	经营者类型（由备案登记机关填写）	其他有限责任公司
住　所	南宫市东部工业聚集区		
经营场所（中文）	南宫市东部工业聚集区		
经营场所（英文）	EASTERN INDUSTRIAL ZONE,NANGONG CITY.		
联系电话	0311-85659588	联系传真	0311-85370188
邮政编码	050000	电子邮箱	249327121@qq.com
工商登记注册日期	2012-9-7	工商登记注册号	130581000012982

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	路文新	有效证件号	132201196705104113
注册资金	壹亿零叁佰万元		（折美元）

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人／个体工商负责人姓名		有效证件号	
企业资产／个人财产			（折美元）

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关

签章

2014 年 04 月 28 日

自理报检单位备案登记证明书

备案登记号：1308601186

企 业 名 称：河北鸿森塑胶科技有限公司

法 定 代 表 人：路文新

组织机构代码：54013624

单 位 地 址：南宫市东部工业聚集区

2013年05月29日

发证机关

发证日期：2013 年 05 月 29 日

国家质量监督检验检疫总局 制

本对外贸易经营者作如下保证：

一、遵守《中华人民共和国对外贸易法》及其配套法规、规章。

二、遵守与进出口贸易相关的海关、外汇、税务、检验检疫、环保、知识产权等中华人民共和国其他法律、法规、规章。

三、遵守中华人民共和国关于核、生物、化学、导弹等各类敏感物项和技术出口管制法规以及其他相关法律、法规、规章，不从事任何危害国家安全和社会公共利益的活动。

四、不伪造、变造、涂改、出租、出借、转让、出卖《对外贸易经营者备案登记表》。

五、在备案登记表中所填写的信息是完整的、准确的、真实的；所提交的所有材料是完整的、准确的、合法的。

六、《对外贸易经营者备案登记表》上填写的任何事项发生变化之日起，30 日内到原备案登记机关办理《对外贸易经营者备案登记表》的变更手续。

以上如有违反，将承担一切法律责任。

对外贸易经营者签字、盖章

年 月 日

注： 1、备案登记表中“组织机构代码”一栏，由企业、组织和取得组织机构代码的个体工商户填写。

2、依法办理工商登记的外国（地区）企业，在经营活动中，承担有限 / 无限责任。依法办理工商登记的个体工商户（独资经营者），在经营活动中，承担无限责任。

3、工商登记营业执照中，如经营范围不包括进口商品的分销业务，备案登记机关应在备注栏中注明“无进口商品分销业务”。