



**ARTICLE NUMBER S1004
MEDICAL NITRILE GLOVES
DUE DILIGENCE FILE**

- Strictly Private & Confidential -

1. PRODUCT IMAGES



包装10包
长40x宽26x高28



TECHNICAL DATA SHEET

Product Name	Single-use Nitrile Patient Examination Gloves		
Picture		Certificate	CE FDA
Sizes	XS S M L XL		
Details	100 pcs/box, 1000pcs/carton, 4 mil medical grade nitrile gloves		
Weight	S-3.7g M-3.9g L-4.0g XL 4.1-4.5 g		
Packaging	Box 24x12.7x6.7 cm S-M-L XL Carton 34x27x25cm S-M-L-XL		
Usage	To conduct medical examination, diagnostic and therapeutic procedures to protect patient and user from cross contamination or infection		
Material	Nitrile (Carboxylated Butadiene Acrylonitrile)		
Cuff Finishing	Beaded		
Colour	Blue		
Type	Ambidextrous		
Surface Finish	Full Textured/Finger Textured		



Specifications sheet

**Medical
Nitrile
Gloves
(Non-Sterile)**
4.0 -4.5 Grams per
gloves not Ordinary
3.5 grams

Specification
9"4.0-4.5 gram per
gloves
Length >240mm +-
10mm
Width 100+- 3
Thickness
Cuff .07mm
Palm .09mm
Finger .11 mm



Specifications:
4.0-4.5Gram weight, Medical Grade Nitrile
gloves
Latex Free
Disposable
Powder Free
Non-Sterilized

ASTM D5151, ASTM D6319,D 6978(Chemo
gloves only), ASTM F1671 viral penetration
Medical Device Regulation EU 2017/425 UNI
EN455 1-2-3- clause 4.4
UNI EN 374-1-2-3-4
Module D
EN420
EN388
AQL 1 /1.5



Product Characteristic								
Weight	Size	Length	Width	Thickness (mm)			Tensile Strength (Mpa)	Ultimate Elongation (%)
		(mm)	(mm)	Cuff	Palm	Finger	≥14	≥500%
9"3.0g	XS	230	75±3	0.05	0.06	0.08	15-20	450-500
	S	230	85±3	0.05	0.06	0.08		
	M	230	95±3	0.05	0.06	0.08		
	L	230	105±3	0.05	0.06	0.08		
	XL	230	115±3	0.05	0.06	0.08		
9"3.5g	Size	Length (mm)	Width (mm)	Thickness (mm)			Tensile Strength (Mpa)	Ultimate Elongation (%)
				Cuff	Palm	Finger	≥14	≥500%
	XS	230	75±3	0.06	0.07	0.09	15-26	500-520
	S	230	85±3	0.06	0.07	0.09		
	M	230	95±3	0.06	0.07	0.09		
	L	230	105±3	0.06	0.07	0.09		
	XL	230	115±3	0.06	0.07	0.09		
9"4.0g	Size	Length (mm)	Width (mm)	Thickness (mm)			Tensile Strength (Mpa)	Ultimate Elongation (%)
				Cuff	Palm	Finger	≥14	≥500%
	XS	230	75±3	0.06	0.07	0.10	29-36	500-540
	S	230	85±3	0.06	0.07	0.10		
	M	230	95±3	0.06	0.07	0.10		
	L	230	105±3	0.06	0.07	0.10		
	XL	230	115±3	0.06	0.08	0.10		
9"4.5g	Size	Length (mm)	Width (mm)	Thickness (mm)			Tensile Strength (Mpa)	Ultimate Elongation (%)
				Cuff	Palm	Finger	≥14	≥500%
	XS	230	75±3	0.08	0.10	0.11	15-28	500-540
	S	230	85±3	0.08	0.10	0.11		
	M	230	95±3	0.08	0.10	0.11		
	L	230	105±3	0.08	0.10	0.11		
	XL	230	115±3	0.08	0.10	0.11		
9"4.8g	Size	Length (mm)	Width (mm)	Thickness (mm)			Tensile Strength (Mpa)	Ultimate Elongation (%)
				Cuff	Palm	Finger	≥14	≥500%
	XS	230	75±3	0.09	0.10	0.11	17-26	500-530
	S	230	85±3	0.09	0.10	0.11		
	M	230	95±3	0.09	0.10	0.11		
	L	230	105±3	0.09	0.10	0.11		
	XL	230	115±3	0.09	0.10	0.11		
9"5.0g	Size	Length (mm)	Width (mm)	Thickness (mm)			Tensile Strength (Mpa)	Ultimate Elongation (%)
				Cuff	Palm	Finger	≥14	≥500%
	XS	230	75±3	0.09	0.11	0.13	18-24	530-560
	S	230	85±3	0.09	0.11	0.13		
	M	230	95±3	0.09	0.11	0.13		
	L	230	105±3	0.09	0.11	0.13		
	XL	230	115±3	0.09	0.11	0.13		
9"5.5g	Size	Length (mm)	Width (mm)	Thickness (mm)			Tensile Strength (Mpa)	Ultimate Elongation (%)
				Cuff	Palm	Finger	≥14	≥500%
	XS	230	75±3	0.10	0.12	0.14	22-25	550-630
	S	230	85±3	0.10	0.12	0.14		
	M	230	95±3	0.10	0.12	0.14		
	L	230	105±3	0.10	0.12	0.14		
	XL	230	115±3	0.10	0.12	0.14		
9"6.6g	Size	Length (mm) (min)	Width (mm)	Thickness (mm)			Tensile Strength (Mpa)	Ultimate Elongation (%)
				Cuff	Palm	Finger	≥14	≥500%
	XS	230	75±3	0.11	0.13	0.16	20-33	530-600
	S	230	85±3	0.11	0.13	0.16		
	M	230	95±3	0.11	0.13	0.16		
	L	230	105±3	0.11	0.13	0.16		
	XL	230	115±3	0.11	0.13	0.16		
9"8mil	Size	Length (mm)	Width (mm)	Thickness (mm)			Tensile Strength (Mpa)	Ultimate Elongation (%)
				Cuff	Palm	Finger	≥14	≥500%
	XS	295	75±3	0.13	0.16	0.21	26-34	510-550
	S	295	85±3	0.13	0.16	0.21		
	M	295	95±3	0.13	0.16	0.21		
	L	295	105±3	0.13	0.16	0.21		
	XL	295	115±3	0.13	0.16	0.21		
12"6.0g	Size	Length (mm) (min)	Width (mm)	Thickness (mm)			Tensile Strength (Mpa)	Ultimate Elongation (%)
				Cuff	Palm	Finger	≥14	≥500%
	XS	295	75±3	0.07	0.09	0.13	31-41	510-540
	S	295	85±3	0.07	0.09	0.13		
	M	295	95±3	0.07	0.09	0.13		
	L	295	105±3	0.07	0.09	0.13		
	XL	295	115±3	0.07	0.09	0.13		
12"7.5g	Size	Length (mm)	Width (mm)	Thickness (mm)			Tensile Strength (Mpa)	Ultimate Elongation (%)
				Cuff	Palm	Finger	≥14	≥500%
	XS	295	75±3	0.09	0.12	0.17	29-41	550-650
	S	295	85±3	0.09	0.12	0.17		
	M	295	95±3	0.09	0.12	0.17		
	L	295	105±3	0.09	0.12	0.17		
	XL	295	115±3	0.09	0.12	0.17		
12"10.4g	Size	Length (mm) (min)	Width (mm)	Thickness (mm)			Tensile Strength (Mpa)	Ultimate Elongation (%)
				Cuff	Palm	Finger	≥14	≥500%
	XS	295	75±3	0.12	0.17	0.20	29-41	550-650
	S	295	85±3	0.12	0.17	0.20		
	M	295	95±3	0.12	0.17	0.20		
	L	295	105±3	0.12	0.17	0.20		
	XL	295	115±3	0.12	0.17	0.20		

2. Contract Manufacture and Power of Attorney for "AIM-X" Brand



Hebei Titans Hongsen Medical Technology Co., Ltd.

TITANS GROUP

Quality And Innovation First

Ref.:331/Edle

Email: info@titans-cn.com

P.O. Box 533, Hi-Tech development zone, Shijiazhuang, Hebei Province

(311)85370099 Phone (311)85370818 Fax

POWER OF ATTORNEY

Nangong city

September 25, 2020

Hereby, "HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO., LTD" from the Eastern Industrial Accumulation Zone, Nangong City, Hebei Province, 051800, People's Republic of China - "Manufacturer" (hereinafter referred to as the Manufacturer), represented by Chairman Lu Wenxin, grants the right to Partnership with "POSTEL-SYSTEMS" LLP (BIN No. 040940004993), registered at the address: 26/1 Zhubanov Street, Nur-Sultan, 010000, Republic of Kazakhstan represented by its director Mukashev Birzhan Talgatovich, acting on the basis of the Charter, to be an authorized representative (hereinafter referred to as the Authorized Representative) of the manufacturer on issues related to products related to personal protective equipment under the trademark (brand) "AIM-X", including the circulation of manufactured medical products in other countries.

To this end, the Authorized Representative has the right to carry out procedures for assessing the conformity of the quality, efficacy and safety of medical devices through technical, toxicological and clinical tests in order to obtain state registration or other registration, as well as make changes and additions to the regulatory and/or working documentation and declare and certify medical devices manufactured by the Manufacturer.

The manufacturer grants the Authorized Representative the right to perform any actions on his behalf related to the above instructions.

This power of attorney is valid until October 1, 2023. With the right to the Authorized Representative to delegate the power of attorney to the official Distributors of the trademark (brand) "AIM-X", partners and other persons.

«HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO., LTD»

(Stamp)

卢文新

/SIGNATURE/



Lu Wenxin

Chairman



Hebei Titans Hongsen Medical Technology Co., Ltd.
TITANS GROUP
Качество и инновации

Иск.:331/Edie
Email: info@titans-cn.com
Индекс: 533, экономическая зона высоких технологий, Шичзячжуан, Провинция Хэбэй
(311)85370099 Телефон (311)85370818 Факс

ГЕНЕРАЛЬНАЯ ДОВЕРЕННОСТЬ

Город Наньгун

« 25 » сентября 2020 года

Настоящим компания «HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO., LTD» из Восточной Промышленной Зоны Накопления, город Нангун, провинция Хэбэй, 051800, Китайская Народная Республика – «Производитель» (далее – Производитель), в лице Председателя Лу Вэньсинь, предоставляет право Товариществу с ограниченной ответственностью «POSTEL-SYSTEMS» (БИН 040940004993), зарегистрированному по адресу: Республика Казахстан, 010000 г. Нур-Султан, ул. Жубанова 26/1 в лице Директора Мукашева Биржана Талгатовича, действующего на основании Устава, быть уполномоченным представителем (далее – Уполномоченный представитель) производителя по вопросам выпускаемой продукции, связанной со средствами индивидуальной защиты продукции под торговой маркой (брендом) «AIM-X», в том числе обращением производимой медицинской продукции на территории других стран.

Для этого Уполномоченный представитель имеет право проводить процедуры оценки соответствия качества, эффективности и безопасности медицинских изделий посредством технических, токсикологических и клинических испытаний в целях получения государственной регистрации или иной регистрации, а также вносить изменения и дополнения в нормативную и/или рабочую документацию и декларировать и сертифицировать медицинские изделия производимые Производителем.

Производитель предоставляет Уполномоченному представителю право выполнять любые действия от его имени связанные с вышеуказанными поручениями.

Настоящая доверенность действительна до 1 октября 2023 года. Уполномоченный представитель имеет право передоверия доверенности официальным Дистрибьюторам торговой марки (бренда) «AIM-X», партнерам и иным лицам.

Компания Hebei Titans Hongsen Medical Technology Co., Ltd (круглая печать компании)

(Штамп)

/ПОДПИСЬ/

Председатель Лу Вэньсинь

Я, Ермаханбетова Акталкын Асылбековна, переводчик Бюро переводов «NT Proff», подтверждаю
верность перевода текста с английского языка на русский язык.



Республика Казахстан, город Нур-Султан.
Двадцать восьмое сентября две тысячи двадцатого года.

Я, Бейсенбаева Арайлым Саматовна, нотариус города Нур-Султан, действующая на основании государственной лицензии № 0002565 выданной от 03 июня 2009 года Комитетом регистрационной службы и оказания правовой помощи Министерства Юстиции Республики Казахстан, свидетельствую подлинность подписи, сделанного переводчиком Ермаханбетовой Актолкын Асылбековной. Личность подписавшей документ установлена, дееспособность и полномочия её проверены.

Зарегистрировано в реестре за №25255

Взыскано государственной пошлины

или сумма, оплаченная частному нотариусу: в соответствии со ст. 30-1 Закона РК «О нотариате» и ст. 611 Налогового кодекса РК

Нотариус:





Hebei Titans Hongsen Medical Technology Co., Ltd.

TITANS GROUP

Quality And Innovation First

Ref.:298/Reese

Email: info@titans-cn.com

P.O. Box 533, Hi-Tech development zone, Shijiazhuang, Hebei Province

(311)85370099 Phone (311)85370818 Fax

TO WHOM IT MAY CONCERN

Date: 9th September 2020

Dear Sir/Madam,

RE: Contract Manufacture for "AIM-X" brand

We, Hebei Titans Hongsen Medical Technology Co., Ltd of Eastern Industrial Accumulation Area, Nangong City, Hebei Province, 051800, The People's Republic of China do hereby confirm that we contract manufacture our polymer based, patient examination gloves for the "AIM-X" brand.

The gloves are powder free, nitrile gloves, our factory has ISO certifications and CE certifications in line with EN374, EN455 as well as others for the sale of our goods in the European Union.

The company is FDA approved, with FDA registration Number 3010582952 and FDA owner/operator number 10045284.

Our range of nitrile gloves have the necessary FDA 510K certifications which can be verified on the FDA register at the hyperlink <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>.

The gloves manufactured for the AIM-X brand are those with the FDA 510K number K163146.

Should you have any questions and/or queries, please do not hesitate to contact us.

Yours faithfully

河北泰能鸿森医疗科技有限公司



Lu Wenxin
Chairman



POWER OF ATTORNEY

Nangong city

September 25, 2020

Hereby, "HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO., LTD" from the Eastern Industrial Accumulation Zone, Nangong City, Hebei Province, 051800, People's Republic of China - "Manufacturer" (hereinafter referred to as the Manufacturer), represented by Chairman Lu Wenxin, grants the right to Partnership with "POSTEL-SYSTEMS" LLP (BIN No. 040940004993), registered at the address: 26/1 Zhubanov Street, Nur-Sultan, 010000, Republic of Kazakhstan represented by its director Mukashev Birzhan Talgatovich, acting on the basis of the Charter, to be an authorized representative (hereinafter referred to as the Authorized Representative) of the manufacturer on issues related to products related to personal protective equipment under the trademark (brand) "AIM-X", including the circulation of manufactured medical products in other countries.

To this end, the Authorized Representative has the right to carry out procedures for assessing the conformity of the quality, efficacy and safety of medical devices through technical, toxicological and clinical tests in order to obtain state registration or other registration, as well as make changes and additions to the regulatory and/or working documentation and declare and certify medical devices manufactured by the Manufacturer.

The manufacturer grants the Authorized Representative the right to perform any actions on his behalf related to the above instructions.

This power of attorney is valid until October 1, 2023. With the right to the Authorized Representative to delegate the power of attorney to the official Distributors of the trademark (brand) "AIM-X", partners and other persons.

«HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO., LTD»

(Stamp)

卢文新

/SIGNATURE/



Lu Wenxin
Chairman

ГЕНЕРАЛЬНАЯ ДОВЕРЕННОСТЬ

город Нангун

«25» сентября 2020 года

Настоящим компания «HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO., LTD» из Восточной промышленной зоны накопления, город Нангун, провинция Хэбэй, 051800, Китайская Народная Республика – «Производитель» (далее – Производитель), в лице Председателя Лу Вэньсинь, предоставляет право Товариществу с ограниченной ответственностью «POSTEL-SYSTEMS» (БИН № 040940004993), зарегистрированному по адресу: Республика Казахстан, 010000, г. Нур-Султан, ул. Жубанова 26/1 в лице Директора Мукашева Биржана Талгатовича действующего на основании Устава, быть уполномоченным представителем (далее – Уполномоченный представитель) производителя по вопросам выпускаемой продукции связанной со средствами индивидуальной защиты продукции под торговой маркой (брендом) «AIM-X», в том числе обращением производимой медицинской продукции на территории других стран.

Для этого Уполномоченный представитель имеет право проводить процедуры оценки соответствия качества, эффективности и безопасности медицинских изделий посредством технических, токсикологических и клинических испытаний в целях получения государственной регистрации или иной регистрации, а также вносить изменения и дополнения в нормативную и/или рабочую документацию и декларировать и сертифицировать медицинские изделия производимые Производителем.

Производитель предоставляет Уполномоченному представителю право выполнять любые действия от его имени связанные с вышеуказанными поручениями.

Настоящая доверенность действительна до 1 октября 2023 года. С правом Уполномоченному представителю передоверия доверенности официальным Дистрибьюторам торговой марки (бренда) «AIM-X», партнерам и иным лицам.

«HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO., LTD»

(Штамп)

路文新

ПОДПИСЬ

Председатель Лу Вэньсинь



3. ISO CERTIFICATE OF FACTORY



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



Date 2018-06-27



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>

SGS INSPECTION REPORT



SGS-P-7.4-01-F02-CR8-HL-
EPM

Report No.: TAOWT00213433 Rev 1

INSPECTION REPORT (Special for Epidemic prevention materials)

IMPORTANT INFORMATION REGARDING THE SCOPE AND LIMITATIONS OF THE INSPECTION AND REPORT

The scope of this report is limited to a VISUAL INSPECTION ONLY for the workmanship and basic function check of the product. Performance index and compliance of the product are NOT included in the scope of this report. This report is a reasonable attempt to identify any obvious or significant defects apparent in those areas of the product fully accessible and visible to the inspector at the time of the inspection. This Report is made solely for the use and benefit of the Client named on the front of this report.

To :	PosTel-Systems LLP/AIM-X Global LLP	Date:	21-Sep-2020
Att :	Abdul Halim Choudhury		
From :	Elvis Dong	E-mail :	elvis.dong@sgs.com

SGS File No.:	CNTAO10288544	Product family view
Buyer :	PosTel-Systems LLP / AIM-X Global LLP	
Supplier :	Aim-X (Suzhou) Protective Engineering & Manufacturing Co., Ltd.	
Manufacturer :	Hebei Titans Hongsen Medical Technology Co., Ltd.	
Style Number:	0001	
Product description:	Single-use Nitrile Patient Examination Gloves	
P.O. Number:	POZCKY2020082700001	
L/C Number:	N/A	
Service performed :	FRI	
Inspection Date :	19-Sep-2020	
Inspection Location :	Shenzhen, Guangdong, China	



Inspection Criteria	
Reference sample provided by	Not Available
Client instruction/specification	YES
SGS WI number	P-INSP-WI-HL-111
Other	N/A

Overall Inspection Conclusion:	Subject to client's evaluation
--------------------------------	--------------------------------

Inspection Summary:	
1. Quantity :	Subject to client's evaluation
2. Style, color :	Subject to client's evaluation
3. Workmanship appearance / function :	Conform
4. Data measurement / field tests:	Subject to client's evaluation
5. Packing :	Subject to client's evaluation
6. Marking / label :	Conform
Problem Remark:	

Inspector: Chuanhong He Factory Representative:

*This document is issued by the Company under its General Conditions of Service accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.
Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

[Rev.01: Apr. 2nd . 2020]

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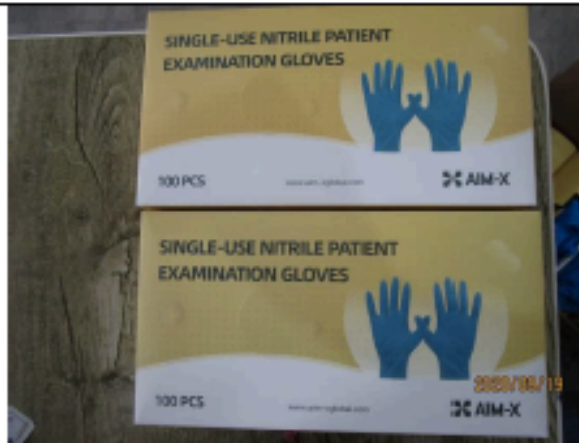
- Found the SIZE L with purple(31 cartons) and blue color (89 cartons)
- Found the SIZE S with purple(12 cartons) and blue color (8 cartons)
- No equipment is available for tensile strength test, thickness, and elongation test and water leakage test.
- No reference sample was available for comparison during inspection.
- Found the color box with color deviation.



Remark : Found the SIZE S with purple and blue color



Remark : Found the SIZE L with purple and blue color



Remark : Found the color boxes with color deviation.



Inspector: Chuanhong He

Factory Representative: _____

"This document is issued by the Company under its General Conditions of Service accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law."

[Rev.01: Apr. 2nd . 2020]

1. Quantity: Subject to client's evaluation

No	Style / Item/ Article	P.O. No.	Order Qty.	Inspection Qty. (Presented Qty. for insp.)		Number of Cartons	
				Packed	Not Packed	Packed	Not packed
1	S	POZCKY20200 82700001	2000	200	0	20	0
2	M			200	0	20	0
3	L			1000	0	100	0
4	XL			600	0	60	0
Total:			2000	2000	0	200	0

2. Style & Color Conformity: Subject to client's evaluation

Comments:

No refer sample was available for comparison during inspection

3. Workmanship Appearance / Functional Inspection Findings: Within AQL

Inspection Method Applied:

ANSI / ASQ Z1.4- 2003 (R2018) , Single sampling plans for normal inspection,

Level II

Sample size: 500pcs

Acceptance Quality Limit (AQL) for: Critical: N/A Major: 1.0 Minor: 1.5

Defect description	Critical	Major	Minor
For S size ,s/s 52 pcs			
No defect	0	0	0
For M size ,s/s 50 pcs			
Black spot on glove	0	0	1
For L size ,s/s 252 pcs			
Dent mark on glove	0	0	2
Dirt mark on glove	0	0	1
Missing color on glove	0	0	1
For XL size ,s/s 146 pcs			
Foreign material on glove	0	0	1
Total defectives:	0	0	6
Maximum allowed:	0	10	14

Inspector: Chuanhong He

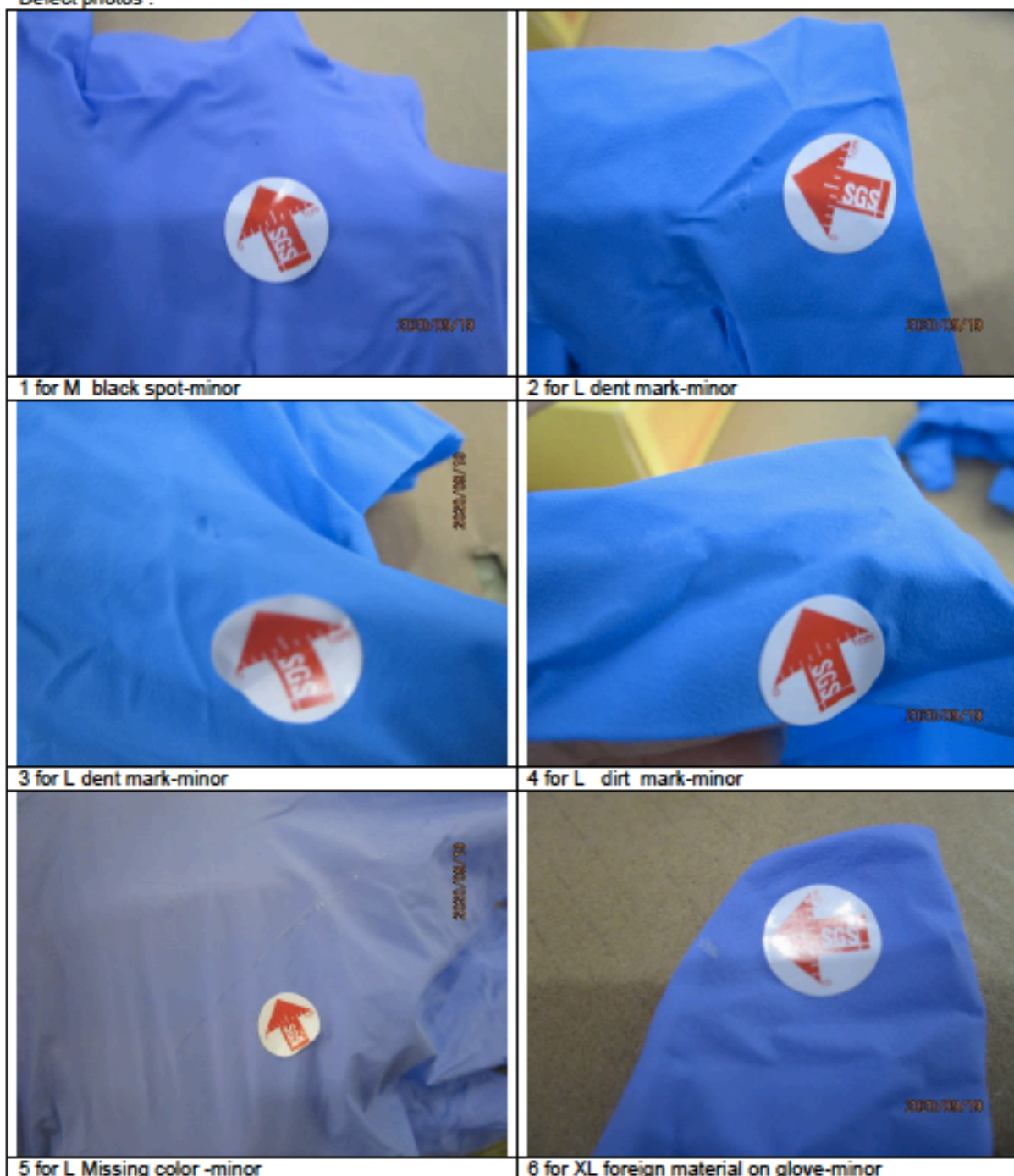
Factory Representative:

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Defect photos :



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4. Product-Specific Data Measurement / Field Test on Reduced Sample Size: Subject to client's evaluation

Check points	Qty	Test Result		Specification/Tolerance
Unit size check	5/size	S	235x82, 235x84, 235x83, 235x82, 235x83mm	S >=240x80+/-10mm M >=240x95+/-10mm L >=240x110+/-10mm XL >=240x>=110mm
		M	240x90,, 238x93, 240x92, 239x90, 240x92mm	
		L	240x105, 245x107, 247x105, 240x106, 245x106mm	
		XL	245x113, 245x115, 246x114, 246x114, 246x115mm	
Unit thickness check	5/size	S	Cuff thickness: 2.24, 2.36, 2.28, 2.32, 2.32 mil	N/A
			Palm thickness: 2.87, 2.76, 2.68, 2.76, 2.83 mil	
			Fingertip thickness: 3.19, 3.74, 3.86, 3.62, 3.27 mil	
		M	Cuff thickness: 2.36, 2.28, 2.36, 2.36, 2.28 mil	
			Palm thickness: 2.76, 2.87, 2.80, 2.76, 2.87 mil	
			Fingertip thickness: 3.98, 4.21, 3.94, 4.33, 4.13 mil	
		L	Cuff thickness: 2.36, 2.36, 2.20, 2.28, 2.28 mil	
			Palm thickness: 2.83, 2.83, 2.87, 2.99, 2.83 mil	
			Fingertip thickness: 3.39, 3.54, 3.62, 3.19, 3.82 mil	
		XL	Cuff thickness: 2.28, 2.28, 2.28, 2.20, 2.56 mil	
			Palm thickness: 3.15, 2.87, 2.68, 2.76, 2.87 mil	
			Fingertip thickness: 3.58, 3.62, 3.39, 3.46, 3.35 mil	
Unit weight check (XL)	5pcs	XL	4.1, 4.1, 4.2, 4.3, 4.4	N/A
Box size check	1/ size	S	24x12.7x6.7cm	N/A
		M	24x12.7x6.7cm	
		L	24x12.7x6.7cm	
		XL	24x12.7x6.7cm	
Number of pcs check per gift box	1/ size	S	102	100pcs
		M	100	
		L	101	
		XL	100	
Carton size check	1/ size	S	34x27x25cm	N/A
		M	34x26.5x25cm	
		L	34x27x25cm	
		XL	34x27x25cm	

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Carton weight check	1/ size	S	4.20kg	N/A
		M	4.55kg	
		L	4.85kg	
		XL	5.25kg	
Carton drop test	1	Passed		76cmx10times
Barcode scan	5	Passed		Can be scan and corrected

5. Packing:

5.1 Individual packing conformity : Subject to client's evaluation

Comments:

Each set (100 pcs) per color box

5.2 Inner packing conformity : Not Applicable

Comments:

N/A

5.3 Export packing conformity : Conform

Comments:

10 sets per 1-wall corrugated cardboard export carton sealed with gummed tape

5.4 Samples selected from carton numbers:

Total selected 14 cartons for inspection and no carton number

6. Marking / Label:

6.1 Bar code: Conform

Pls refer to photo

6.2 Shipping mark conformity: Conform

Comments:

Pls refer to photo

6.3 Marking & label conformity: Conform

Comments:

Pls refer to photo

7. Informative Remark:

Nil

Inspector: Chuanhong He

Factory Representative:

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8. Inspection Environment:

Lighting :	Room lighting Sufficient
Inspection place :	Warehouse
Inspection done on:	Table
Cleanliness :	Clean
Weather condition:	Rainy
Cargo storage:	Orderly, easy to count

9. Attachment



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Factory Representative: _____

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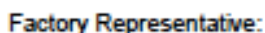


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These high-quality disposable gloves offer strength, durability and barrier protection that does not occur. They have been designed for maximum sensitivity, dexterity and comfort, and fatigue when in use for extended periods of time. 100% latex free and powder free, a great alternative for those sensitive to latex. Manufactured for AIM-X by Hebei Trans Hongsen Medical Technology Co Ltd, Hebei, 051800, China. FDA Registration No: 3010582952 FDA Owner/Operator No: 10054284 510K No: K161146 CE Registration Number: (TUV Rheinland) BP 60101629 0002 (EN374) Certificate No: (TUV Rheinland) AK 60090940 (EN455) 2020/09/19	These high-quality disposable gloves offer strength, durability and barrier protection that prevents skin contact to ensure contamination. They have been designed for maximum sensitivity, dexterity and comfort, and offer increased elasticity and flexibility to reduce the risk of breakage over time. 100% latex free and powder free, a great alternative for those sensitive to latex proteins. Manufactured for AIM-X by Hebei Trans Hongsen Medical Technology Co Ltd, Hebei, 051800, China. FDA Registration No: 3010582952 FDA Owner/Operator No: 10054284 510K No: K161146 CE Registration Number: (TUV Rheinland) BP 60101629 0002 (EN374) Certificate No: (TUV Rheinland) AK 60090940 (EN455) 2020/09/19
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(27)	(28)

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(29)



(30)



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(32)



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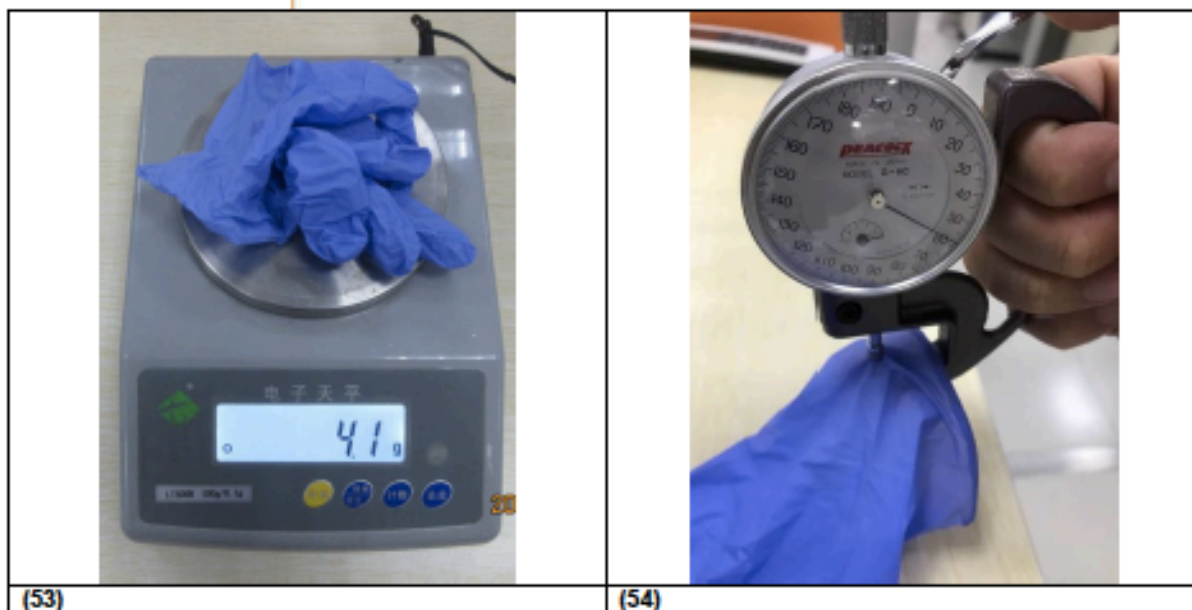


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End of Report

Inspector: Chuanhong He Factory Representative: _____

CERTIFICATE OF CONFORMITY

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Hebei Titans Hongsen Medical Technology Co.,Ltd
Name and address of the manufacturer: / Eastern Industrial Zone, Nangong City, Xingtai City, 051800
Nom et adresse du fabricant: / Hebei, China
Nome e indirizzo del fabbricante:

Wir, der Hersteller, erklären, dass wir allein für die folgenden Verantwortlichkeiten verantwortlich sind: /

We, the manufacturer declare under our sole responsibility that /

Nous, le fabricant, déclarons être seuls responsables des responsabilités suivantes: /

Noi, il produttore, dichiariamo di essere i soli responsabili delle seguenti responsabilità:

das Medizinprodukt: /

the medical device: /

le dispositif médical: /

il dispositivo medico:

Single-use Nitrile Patient Examination Gloves

Model: (XS,S,M,L,XL)

der Klasse: /

of class: /

de la classe: /

di classe:

Class I

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il "rapporto di ispezione finale" del prodotto.

Konformitätsbewertungsverfahren: /

Conformity assessment procedure: /

Procédure d'évaluation de la conformité: /

Procedura di valutazione della conformità:

Richtlinie 93/42/EWG Anhang VII

Directive 93/42/EEC Annex VII

Directive 93/42/CEE Annexe VII

Direttiva 93/42/CEE senza Allegato VII

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

EC REP : MedNet EC-REP GmbH ·

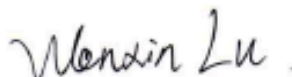
Address : Borkstrasse 10 , 48163 Muenster ,Germany



Nangong, Mar. 30th 2020

Ort, Datum / Place, date /

Lieu, date / Luogo, data


Wenxin Lu Chairman

Name und Funktion / Name and function /

Nom et fonction / Nome e funzione

CE DECLARATION OF CONFORMITY

Manufacturer

Name: Hebei Titans Hongsen Medical Technology Co., Ltd

Address: Eastern Industrial Zone, Nangong City, Xingtai City, Hebei, China

Declares that the MDD described hereafter

Products name and Model:

Disposable Nitrile Examination Gloves

XS, S, M, L and XL

Meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EEC

Examination gloves are classified as Class I medical devices in accordance with the rules set out in Annex IX

Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN455-3:2015, NISO14971:2012, EN ISO 13485:2016.

Conformity assessment procedure: Annex VII of Medical Device Directive 93/42/EEC

The CE declaration of conformity is issued under the sole responsibility of Hebei Titans Hongsen Medical Technology Co., Ltd

The products can be placed the following CE mark.



Signature: Feng Shuangyan

Date: April 23, 2019

Quality Supervision Organization

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
Am Grauen Stein · 51105 Köln

EN374-1-2-3-4

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

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.



PSB Singapore

Add value.
Inspire trust.

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		



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

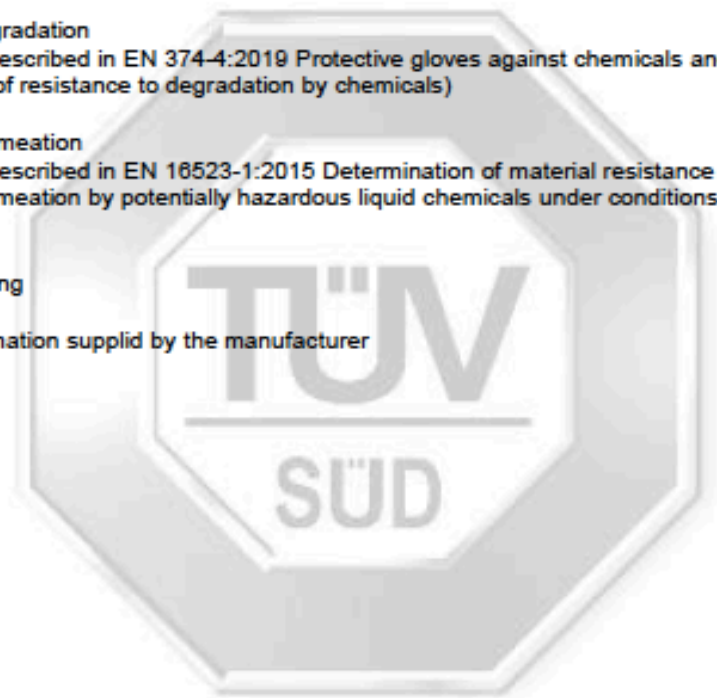
Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01
Singapore 118221
www.tuv-sud.com

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 18523-1:2015 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 supplied by the manufacturer



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



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	
				Glove 2	
				Glove 3	
				Average	
				Standard Deviation	
			Size M	Glove 1	NA
				Glove 2	
				Glove 3	
				Average	
				Standard Deviation	
			Size L	Glove 1	NA
				Glove 2	
				Glove 3	
				Average	
				Standard Deviation	
			Size XL	Glove 1	NA
				Glove 2	
				Glove 3	
				Average	
				Standard Deviation	

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



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 18523-1:2015, 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	
			Glove 2	
			Glove 3	
			Mean Value	
			Lowest Value	
			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:	NT
		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
Inferred results			Not tested

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



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

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



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:

- 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.
- 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.
- 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 ($23^{\circ}\text{C} \pm 2^{\circ}\text{C}$). 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.

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



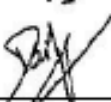
REMARKS (cont'd):

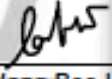
4. Table A Classification of Glove Levels According to Breakthrough Time for Clause 5.4 Permeation

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 $\mu\text{g}/\text{cm}^2/\text{min}$.

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)

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



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

July 2011



Business Stream Products
Certification Department



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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

Dipl.-Ing. C. Albrecht

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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

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Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schüssler

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490

Z E R T I F I K A T
EU-Baumusterprüfbescheinigung
Verordnung 2016/425/EU
Persönliche Schutzausrüstung



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

Datum 12.08.2020

Benannte Stelle



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.

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

C E R T I F I C A T E
EU Type-Examination Certificate
Regulation 2016/425/EU
Personal Protective Equipment



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

Date 12.08.2020

Notified Body



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

Report No. : CH:TX:9420047921-1

Revised report.
DATE : 09/10/2018

HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO LTD
EASTERN INDUSTRIAL ZONE NANGONG CITY
XINGTAI CITY, HEBEI, CHINA 051800
A/C F619201 SGS-CSTC STANDARDS TECHNICAL SERVICES (TIANJIN) CO., LTD.
CONTACT PERSON :

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

SAMPLE DESCRIPTION GLOVES
LOW WEIGHT POWDER FREE BLUE NITRILE EXAMINATION GLOVES
COLOUR BLUE
COUNTRY OF DESTINATION EUROPE
COUNTRY OF ORIGIN CHINA
PHOTO APPENDIX.



SAMPLE RECD ON

17/09/2018

TESTING PERIOD : 17/09/2018 - 29/09/2018

Summary of Test Results/Conclusion		
Test Method / Standard	Clause/Test Name	Status / Performance Level
EN 420:2003+A1:2009	Protective gloves - General requirements	
	Sizing	Refer enclosed pages.
	Dexterity	Performance level 5
	pH Value	Pass
EN 374-2:2014	Protective gloves against chemicals and micro-organisms: Determination of resistance penetration	
	Clause 4.1 - Air leak test	Pass
	Clause 4.2 - Water leak test	Pass
EN 16523-1:2015	Permeation by Liquid chemical under conditions of continuous contact.	
	Methanol	Level - 0
	Toluene	Level - 0
	Diethylamine	Level - 0
	n-Heptane	Level - 0
	Sodium hydroxide 40%	Level - 6
EN 374-4:2013	Sulphuric acid 96%	Level - 0
	Resistance to Degradation by Chemicals	
	Methanol	Refer results.
	Toluene	Refer results.
	Diethylamine	Refer results.
	n-Heptane	Refer results.
	Sodium hydroxide 40%	Refer results.
	Sulphuric acid 96%	Refer results.

Per pro SGS India Private Ltd.

K. PACHAIYAPPAN
ASST. MANAGER

Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

Test report revised to correct the thickness.

This report cancels and supersedes report no. 9420047921 Dated 29/09/2018 Issued by SGS India

JOE No. : 1842625471

Page 1 of 4

Control No.: 9425051387

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TEST REPORT

Report No. : CH:TX:9420047921-1

Revised report
DATE : 09/10/2018



RESULTS

EN 420 : 2003+A1: 2009 Protective Gloves – General requirements and test methods

Clause	Test Name	Result				Average	Standard sizing
5.1	Sizing Declared size XS Circumference (mm) Length (mm)	164 243	162 244			163.0 243.5	6
	Declared size S Circumference (mm) Length (mm)	175 242	174 241			174.5 241.5	6½
	Declared size M Circumference (mm) Length (mm)	190 240	192 244			191.0 242.0	7½
	Declared size L Circumference (mm) Length (mm)	206 240	208 241			207.0 240.5	8
	Declared size XL Circumference (mm) Length (mm)	224 240	226 242			225.0 241.0	8½*
5.2	Dexterity Smallest Pin Diameter (mm)	5	5	5	5	5	Performance level 5

* → Fit for special purpose.

EN 374-2 : 2014 Protective gloves against chemicals and micro-organisms – Part-2: Determination of resistance penetration

Clause	Test Name	Test Results		Performance level
4.1	Air leak Test (Air Pressure Used : 0.5 kPa)	Specimen #	Leakage	Pass
		Size XS	No Leakage	
		Size S	No Leakage	
		Size M	No Leakage	
		Size L	No Leakage	
4.2	Water leak test	Specimen #	Leakage	Pass
		Size XS	No Leakage	
		Size S	No Leakage	
		Size M	No Leakage	
		Size L	No Leakage	
		Size XL	No Leakage	

**** End of Page****

TEST REPORT

Report No. : CH:TX:9420047921-1

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DATE : 09/10/2018



RESULTS

pH VALUE

With reference to ISO 3071:2005/Analysis by pH meter
Extraction Solution : KCL

GLOVES – BLUE

Value 6.8 3.5 - 9.5

Note : pH value of extraction medium : 5.0 – 7.5
Temperature of the extraction solution : 25±2°C

Note: Requirements given as per EN 420:2003 +A1:2009 (Clause: 4.3.2).

EN 16523-1:2015 Determination of material resistance to permeation by chemicals – Part-1: Permeation by Liquid chemical under conditions of Continuous contact.

Chemical CAS NO	Loop system/collection medium	Analytical technique used	Mean thickness (mm)	NBT at NPR 1.0 μcm^2 min ⁻¹ (minutes)	Performance level accordance to EN ISO 374-1: 2016 Table 1	Observation
Methanol 67-56-1	Open loop/ Nitrogen	Continuous measurement With GC-FID	0.05 0.04 0.05	<1 <1 <1	Level - 0	Moderate swelling
Toluene 108-88-3	Open loop/ Nitrogen	Continuous measurement With GC-FID	0.04 0.04 0.05	<1 <1 <1	Level - 0	Severe swelling
Diethylamine 109-89-7	Open loop/ Nitrogen	Continuous measurement With PID	0.04 0.05 0.04	<1 <1 <1	Level - 0	Severe swelling
n-Heptane 142-85-5	Open loop/ Nitrogen	Continuous measurement With GC-FID	0.04 0.04 0.05	4 5 6	Level - 0	Slight swelling
Sodium hydroxide 40% 1310-73-2	Closed loop/ Grade 3 water	Continuous measurement With Conductivity electrode	0.05 0.05 0.04	> 480 > 480 > 480	Level - 6	No change
Sulphuric acid 96% 7664-93-9	Closed loop/ Grade 3 water	Continuous measurement With Conductivity electrode	0.04 0.05 0.04	2 3 2	Level - 0	Severe swelling & colour change

**** End of page****

TEST REPORT

Revised report.

Report No. : CH:TX:9420047921-1

DATE : 09/10/2018



RESULTS

EN 374-4:2013 Protective Gloves against Chemicals and Micro Organisms – Determination of resistance to degradation by chemicals

Chemical / CAS NO	Exposure Duration	Test Results		Observation
		Percentage change in puncture resistance		
Methanol 67-56-1	60±5 minutes	<u>Glove sample</u>	<u>Result (%)</u>	Severe swelling
		1	72.3	
		2	58.4	
		3	67.7	
		Mean	66.1	
		Standard Deviation	7.051	
Toluene 108-88-3	60±5 minutes	<u>Glove sample</u>	<u>Result (%)</u>	Severe swelling
		1	81.4	
		2	78.9	
		3	81.8	
		Mean	80.7	
		Standard Deviation	1.571	
Diethylamine 109-89-7	60±5 minutes	<u>Glove sample</u>	<u>Result (%)</u>	Severe swelling
		1	94.7	
		2	91.1	
		3	89.2	
		Mean	91.7	
		Standard Deviation	2.826	
n-Heptane 142-85-5	60±5 minutes	<u>Glove sample</u>	<u>Result (%)</u>	Moderate swelling
		1	38.1	
		2	40.0	
		3	38.1	
		Mean	38.7	
		Standard Deviation	1.096	
Sodium hydroxide 40% 1310-73-2	60±5 minutes	<u>Glove sample</u>	<u>Result (%)</u>	No change
		1	-6.0	
		2	-15.1	
		3	-4.8	
		Mean	-8.6	
		Standard Deviation	5.662	
Sulphuric acid 96% 7664-93-9	60±5 minutes	<u>Glove sample</u>	<u>Result (%)</u>	Complete degradation
		1	100	
		2	100	
		3	100	
		Mean	100	
		Standard Deviation	0.000	

**** End of Report****



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



Authorised by

Tom Tom

SGS FIMKO OY, Notified Body 0598
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extent of the law.

Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH • 90431 Nürnberg

Ms. Ming Liu
TÜV Rheinland (China) Ltd.
Unit 707, AVIC Building
No. 10B, Central Road
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 Zone
CHI 051800 Nangong City, Hebei

Kind regards

Certification body



Dipl.-Ing. C. Albrecht

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
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Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nürnberg HRB 26013
UST-ID Nr.: DE 811835490

EN 455-1-2-3, Clause 4.4

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HOME » HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO., LTD. » CERTIFICATE NO. AK 60090940

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Certificate No. AK 60090940

Certificate Holder:	Hebei Titans Hongsen Medical Technology Co., Ltd. Eastern Industrial Zone Nangong City, Xingtai City 051800 Hebei China (Mainland)
Certificate Number:	AK 60090940
Order Number:	3091541
Certified Product:	Gloves (medizinische Einmalhandschuhe) Model Designation: Titanfine
Fulfilled Standards:	EN 455-1:2000 EN 455-3:2006 The standard(s) listed here reflect the status at the time of the release of this certificate.
Date of Issue:	2013-12-19
Certificate Type:	Certificate of Conformity The certificate of conformity (CoC) refers to the product specified in the certificate. The certificate demonstrates that a product sample was tested and evaluated at a specific time, and found to be in conformity with the assessment requirements specified in the certificate. A CoC is relevant to importers and exporters to prove that products comply with local regulations. This certificate does not imply an assessment of the product's production and does not permit the use of a TÜV Rheinland test mark.

Further Information

[Request more information on Hebei Titans Hongsen Medical Technology Co., Ltd.](#)

[All product certificates of Hebei Titans Hongsen Medical Technology Co., Ltd.](#)

[All certified management systems of Hebei Titans Hongsen Medical Technology Co., Ltd.](#)

TÜV RHEINLAND CORPORATE WEBSITE

SITEMAP

DATA PRIVACY DECLARATION

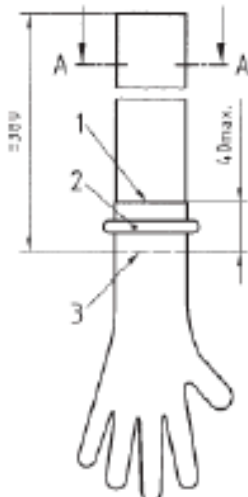
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Prüfbericht-Nr.: 21231019_001
Test Report No.:

Seite 4 von 9
Page 4 of 9

Absatz	EN 455-1; EN 455-2; EN 455-3, clause 4.4	Messergebnisse - Bemerkungen	Bewertung
Clause	Anforderungen - Prüfungen / Requirements - Tests	Measuring results - Remarks	Evaluation

	Der Originaltext wird nur auszugsweise wieder gegeben. Details sind dem Original-Dokument zu entnehmen. <i>The original text is reproduced only in part. For details, be referred to the original document.</i>								
	EN 455-1 - Medizinische Handschuhe zum einmaligen Gebrauch - Teil 1: Anforderungen und Prüfungen auf Dichtheit <i>EN 455-1 - Medical gloves for single use - Part 1: Requirements and testings for freedom from holes</i>								
1	Anwendungsbereich <i>Scope</i>								
2	Normative Verweisungen <i>Normative references</i>								
3	Begriff <i>Terms and definition</i>								
4	Anforderung <i>Requirement</i>								
	Medizinische Handschuhe zum einmaligen Gebrauch müssen dicht sein. <i>Medical gloves for single use shall not leak when tested</i>								
5	Wasserhalteprüfung zur Feststellung von Undichtigkeiten <i>Watertightness test for detection of holes</i>								
Bild 1	Die Handschuhe müssen entsprechend der Qualitätsgrenzlage (AQL) bei der Prüfung dicht sein. <i>Glove must be waterproof upon the examination in according to quality limit (AQL).</i> Untersuchungsniveau und akzeptables Qualitätsniveaus / <i>Inspection level and adequate assesment level of quality:</i> S4 Wasser-Leck-Prüfung / <i>water leak test</i> 	geprüfte Menge/ <i>tested quantity:</i> 10 Stück/pieces akzeptierte Fehler/ <i>accepted defects:</i> 0 Stück/pieces Wasser-Leck-Prüfung / <i>Water leakage</i> <table><tr><td></td><td>dicht/ not leaking</td><td>undicht/ leaking</td></tr><tr><td></td><td>10</td><td>0</td></tr></table>		dicht/ not leaking	undicht/ leaking		10	0	P ☒ F ☐ N/A ☐ N/T ☐
		dicht/ not leaking	undicht/ leaking						
	10	0							

Prüfbericht-Nr.: 21231019_001
Test Report No.:

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Absatz	EN 455-1; EN 455-2; EN 455-3, clause 4.4	Messergebnisse - Bemerkungen	Bewertung																																	
Clause	Anforderungen - Prüfungen / Requirements - Tests	Measuring results - Remarks	Evaluation																																	
	EN 455-2 - Medizinische Handschuhe zum einmaligen Gebrauch - Teil 1: Anforderungen und Prüfung der physikalischen Eigenschaften EN 455-2 - Medical gloves for single use - Part 1: Requirements and testing for physical properties																																			
1	Anwendungsbereich Scope																																			
2	Normative Verweisungen Normative references																																			
3	Begriffe Terms and definition																																			
4	Maße Dimensions																																			
	Maße der Operationshandschuhe Dimensions of surgical gloves																																			
Tab. 1	<table><tr><th>Größe Size</th><th>Median der Länge Median length [mm]</th><th>Median der Breite Median width [mm]</th></tr><tr><td>5</td><td>≥ 250</td><td>67 ± 4</td></tr><tr><td>5,5</td><td>≥ 250</td><td>72 ± 4</td></tr><tr><td>6</td><td>≥ 260</td><td>77 ± 5</td></tr><tr><td>6,5</td><td>≥ 260</td><td>83 ± 5</td></tr><tr><td>7</td><td>≥ 270</td><td>89 ± 5</td></tr><tr><td>7,5</td><td>≥ 270</td><td>95 ± 5</td></tr><tr><td>8</td><td>≥ 270</td><td>102 ± 6</td></tr><tr><td>8,5</td><td>≥ 280</td><td>108 ± 6</td></tr><tr><td>9</td><td>≥ 280</td><td>114 ± 6</td></tr><tr><td>9,5</td><td>≥ 280</td><td>121 ± 6</td></tr></table>	Größe Size	Median der Länge Median length [mm]	Median der Breite Median width [mm]	5	≥ 250	67 ± 4	5,5	≥ 250	72 ± 4	6	≥ 260	77 ± 5	6,5	≥ 260	83 ± 5	7	≥ 270	89 ± 5	7,5	≥ 270	95 ± 5	8	≥ 270	102 ± 6	8,5	≥ 280	108 ± 6	9	≥ 280	114 ± 6	9,5	≥ 280	121 ± 6	---	P ☐ F ☐ N/A ☒ N/T ☐
Größe Size	Median der Länge Median length [mm]	Median der Breite Median width [mm]																																		
5	≥ 250	67 ± 4																																		
5,5	≥ 250	72 ± 4																																		
6	≥ 260	77 ± 5																																		
6,5	≥ 260	83 ± 5																																		
7	≥ 270	89 ± 5																																		
7,5	≥ 270	95 ± 5																																		
8	≥ 270	102 ± 6																																		
8,5	≥ 280	108 ± 6																																		
9	≥ 280	114 ± 6																																		
9,5	≥ 280	121 ± 6																																		
	Maße der Untersuchungshandschuhe Dimensions of examination/procedure gloves																																			
Tab. 2	<table><tr><th>Größe Size</th><th>Median der Länge Median length [mm]</th><th>Median der Breite Median width [mm]</th></tr><tr><td>Extra klein/ extra small</td><td rowspan="5">≥ 240</td><td>≤ 80</td></tr><tr><td>Klein/ small</td><td>80 ± 10</td></tr><tr><td>Mittelgroß/ medium</td><td>95 ± 10</td></tr><tr><td>Groß/ large</td><td>110 ± 10</td></tr><tr><td>Extra groß/ extra large</td><td>≥ 110</td></tr></table>	Größe Size	Median der Länge Median length [mm]	Median der Breite Median width [mm]	Extra klein/ extra small	≥ 240	≤ 80	Klein/ small	80 ± 10	Mittelgroß/ medium	95 ± 10	Groß/ large	110 ± 10	Extra groß/ extra large	≥ 110	<table><tr><th colspan="2">Median der Länge/ Median length: 246 mm</th></tr><tr><th>Größe Size</th><th>Median der Breite Median width [mm]</th></tr><tr><td>Extra klein/ extra small</td><td>78</td></tr><tr><td>Klein/ small</td><td>86</td></tr><tr><td>Mittelgroß/ medium</td><td>96</td></tr><tr><td>Groß/ large</td><td>107</td></tr><tr><td>Extra groß/ extra large</td><td>115</td></tr></table>	Median der Länge/ Median length: 246 mm		Größe Size	Median der Breite Median width [mm]	Extra klein/ extra small	78	Klein/ small	86	Mittelgroß/ medium	96	Groß/ large	107	Extra groß/ extra large	115	P ☒ F ☐ N/A ☐ N/T ☐					
Größe Size	Median der Länge Median length [mm]	Median der Breite Median width [mm]																																		
Extra klein/ extra small	≥ 240	≤ 80																																		
Klein/ small		80 ± 10																																		
Mittelgroß/ medium		95 ± 10																																		
Groß/ large		110 ± 10																																		
Extra groß/ extra large		≥ 110																																		
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Extra groß/ extra large	115																																			

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Absatz	EN 455-1; EN 455-2; EN 455-3, clause 4.4	Messergebnisse - Bemerkungen	Bewertung
Clause	Anforderungen - Prüfungen / Requirements - Tests	Measuring results - Remarks	Evaluation
5	Reißkraft Strength		
5.1	Allgemeines General		
	Unterschiedliche Handschuhmaterialien verlangen unterschiedliche Anforderungen für die Reißkraft, um annehmbare Eigenschaften zu gewährleisten. Die absoluten Reißkraftwerte korrelieren nicht direkt mit der Gebrauchstauglichkeit. Die Auswahl angemessener Handschuhmaterialien für den beabsichtigten Gebrauch muss Teil des Risikomanagements sein. Different glove materials require different force at break requirements to ensure an acceptable performance. Absolute force at break values do not directly correlate with the in use performance. Selection of appropriate glove materials for the intended application shall be part of the risk management process.		
5.2	Reißfestigkeit Force at break		
Tab. 3	zu prüfen im Anlieferungszustand und nach Belastung to test in delivery conditions and after challenge testing		P ☒ F ☐ N/A ☐ N/T ☐
		Reißkraft Force at break [N]	
	Operationshandschuhe Surgical gloves		
	- aus Naturkautschuklatex from natural rubber latex	≥ 9,0	
	- aus allen anderen elastomeren Materialien from all other elastomeric materials	≥ 9,0	
	Untersuchungshandschuhe Examination/ procedure gloves		
	- aus elastomeren Materialien außer Nitril from elastomeric materials except nitrile	≥ 6,0	
	- aus Nitril from nitrile	≥ 6,0	
	- aus thermoplastischen Materialien from thermoplastic materials	≥ 3,6	

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Absatz	EN 455-1; EN 455-2; EN 455-3, clause 4.4	Messergebnisse - Bemerkungen	Bewertung	
Clause	Anforderungen - Prüfungen / Requirements - Tests	Measuring results - Remarks	Evaluation	
	EN 455-3 - Medizinische Handschuhe zum einmaligen Gebrauch - Teil 3: Anforderungen und Prüfung für die biologische Bewertung EN 455-3 - Medical gloves for single use - Part 3: Requirements and testing for biological evaluation			
1	Anwendungsbereich Scope			
2	Normative Verweisungen Normative references			
3	Begriff Terms and definition			
4	Anforderung Requirement			
4.1	Allgemeines General			
	Medizinische Einmalhandschuhe müssen nach den Normen der Reihe EN ISO 10993 beurteilt werden. Teil 1 dieser Reihe beschreibt allgemeine Prinzipien zur Regelung der biologischen Bewertung von Medizinprodukten und muss zur Auswahl der entsprechenden Prüfverfahren in den anderen Teilen der Serie herangezogen werden. Ein Risikomanagementprozess nach EN ISO 14971 muss eingeführt sein. Medical gloves for single use shall be evaluated as described in the EN ISO 10993 series. Part 1 of this series describes the general principles governing the biological evaluation of medical devices and shall be used to select the appropriate tests as described in other parts of the series. A risk management process in accordance with EN ISO 14971 shall be established.	---	P	☐
			F	☐
			N/A	☐
			N/T	☒
4.2	Chemikalien Chemicals			
	Handschuhe dürfen nicht mit Talkum (Magnesiumsilikat) gepudert sein. Gloves shall not be dressed with talcum powder (magnesium silicate).	---	P	☐
			F	☐
			N/A	☒
			N/T	☐
	Soweit technische Alternativen bestehen müssen Chemikalien, die als allergen bekannt sind, vermieden werden. Wenn möglich, müssen erlaubte Grenzwerte für extrahierbare Chemikalienreste unter Anwendung der EN ISO 10993-17 festgelegt werden, wobei diese Grenzwerte einzuhalten sind. Falls dies nicht möglich ist, muss die Höhe der chemischen Rückstände „so gering wie vernünftigerweise praktikabel“ (ALARP = as low as reasonably practicable, siehe EN ISO 14971) sein.	---	P	☐
			F	☐
			N/A	☐
			N/T	☒

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Absatz	EN 455-1; EN 455-2; EN 455-3, clause 4.4	Messergebnisse - Bemerkungen	Bewertung						
Clause	Anforderungen - Prüfungen / Requirements - Tests	Measuring results - Remarks	Evaluation						
	<i>Chemicals known to be allergenic shall be avoided if technical alternatives exist. Wherever possible allowable limits for leachable residual chemicals shall be established using EN ISO 10993-17 and these limits shall be complied with. Wherever this is not possible, the residual chemicals level shall be "As Low As Reasonably Practicable" (ALARP – see EN ISO 14971).</i>								
	Der Hersteller muss auf Anfrage eine Liste von chemischen Inhaltsstoffen zur Verfügung stellen, die im Herstellungsprozess zugesetzt wurden, oder bekanntermaßen entstehen (z. B. Akzeleratoren, Antioxidantien, Biozide) und von denen aufgrund von aktuellen Daten bekannt ist, dass sie unerwünschte gesundheitliche Folgen hervorrufen können. <i>The manufacturer shall disclose, upon request, a list of chemical ingredients either added during manufacturing or already known to be present in the product such as accelerators, antioxidants and biocides, that are known to cause adverse health effects based on current data.</i>	---	P ☐ F ☐ N/A ☐ N/T ☒						
4.3	Endotoxine Endotoxins								
	Wenn der Hersteller sein Produkt mit „niedriger Endotoxingehalt“ kennzeichnet, muss die Endotoxin-Kontamination überwacht werden. Solchermaßen gekennzeichnete Handschuhe dürfen nicht mehr als 20 Endotoxin-Einheiten (EU) an Endotoxin je Handschuhpaar enthalten. <i>The manufacturer shall monitor the endotoxin contamination of sterile gloves if the gloves are labelled with 'low endotoxin content'. For such labelled gloves the endotoxin content shall not exceed the limit of 20 endotoxin units per pair of gloves.</i>	---	P ☐ F ☐ N/A ☐ N/T ☒						
4.4	Puder Powder								
	Der gesamte Anteil des Puderrückstands, darf für puderfreie Handschuhe nicht mehr als 2 mg je Handschuh betragen. Jeder Handschuh, der mehr als 2 mg Puder enthält, ist ein gepuderter Handschuh. <i>For powder free gloves the total quantity of powder residues shall not exceed 2 mg per glove. Any glove containing more than 2 mg powder is a powdered glove.</i>	<table><tr><td colspan="2">/^a</td></tr><tr><td></td><td>Pudergehalt quantity of powder [mg]</td></tr><tr><td>Vinyl (synthetic) Examination Gloves</td><td><1</td></tr></table>	/ ^a			Pudergehalt quantity of powder [mg]	Vinyl (synthetic) Examination Gloves	<1	P ☒ F ☐ N/A ☐ N/T ☐
/ ^a									
	Pudergehalt quantity of powder [mg]								
Vinyl (synthetic) Examination Gloves	<1								

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Absatz	EN 455-1; EN 455-2; EN 455-3, clause 4.4	Messergebnisse - Bemerkungen	Bewertung
Clause	Anforderungen - Prüfungen / Requirements - Tests	Measuring results - Remarks	Evaluation
4.5	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: <i>Lowry- Prüfmethode</i> so gering wie vernünftigerweise praktikabel (ALARP) <i>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)</i>	---	P ☐ F ☐ N/A ☒ N/T ☐
	<u>Anmerkung zum Proteingehalt</u> Bericht vom 13./14. April 2005 über die 117. Sitzung der Vorläufigen Kunststoffkommission des BfR (Bundesinstitut für Risikobewertung): Allergien bei Kontakt mit latexhaltigen Bedarfsgegenständen, Abgabe von löslichen Proteinen Im Hinblick auf die Begrenzung des Proteingehaltes hatte das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) vor einigen Jahren im Rahmen einer Risikobewertung für medizinische Handschuhe aus Naturkautschuklatex festgestellt, dass Proteingrenzwerte, unterhalb derer ein Risiko auszuschließen ist, mittels klinischer Daten derzeit nicht angegeben werden können. Unter Berücksichtigung der analytischen Methodik wurde aus klinischer Sicht die Einhaltung eines Wertes von 30 mg/kg (30 µg/g) als geeignete Maßnahme zur Risikominimierung angesehen. Angeichts der vorliegenden Untersuchungsergebnisse der im Handel befindlichen Produkte (Bedarfsgegenstände aus Naturkautschukmaterialien) sprach sich die Kunststoffkommission dafür aus, als ersten Schritt zur Minimierung des Risikos einen Richtwert von 200 mg löslichem Protein pro kg (200 µg löslichem Protein pro g) Bedarfsgegenstand vorübergehend zu dulden (2002). <i>Note on protein content</i> <i>Report of 13./14. April 2005 about the meeting of the Interim Commission of Plastics of the BfR (Federal Institute for Risk Assessment):</i> <i>Allergies on contact with latex-containing consumer products, distribution of soluble proteins</i> <i>With regards to the limitation of the protein content, the Federal Institute for Drugs and Medical Devices (BfArM) had found a risk assessment for medical gloves made of natural rubber latex a few years ago, that protein thresholds below which a risk is ruled out by clinical data currently can not be specified.</i> <i>Taking into account the analytical methodology adherence to a value of 30 mg/kg (30 µg/g) was regarded as an appropriate measure to minimize the risk from a clinical perspective.</i> <i>Given the present investigation results of the marketed products (commodities made of natural rubber material), the Commission of Plastics spoke in favor of a first step towards minimizing the risk of a guideline, to tolerate a value of 200 mg soluble protein per kg (200 µg soluble protein per g) of article for the moment (2002).</i>		
4.6	Kennzeichnung Labeling		
			P ☐ F ☐ N/A ☒ N/T ☐

Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Ms. Ming Liu
TÜV Rheinland (China) Ltd.
Unit 707, AVIC Building
No. 10B, Central Road
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 Zone
CHI 051800 Nangong City, Hebei

Kind regards

Certification body



Dipl.-Ing. C. Albrecht

TÜV Rheinland
LGA Products GmbH

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90431 Nürnberg

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Jörg Mähler, Spokesman

Dipl.-Kfm.
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Nürnberg HRB 26013
UST-ID Nr.: DE 811835490

Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Mr. Wenxin Lu
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Technology Co., Ltd.
Eastern Industrial Accumulation Zone
051800 NANGONG CITY, HEBEI
CHINA

Contact

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

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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
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



Dipl.-Ing. C. Albrecht

Test sample: stored by warehouse Leipzig

TÜV Rheinland
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Board of Management

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UST-ID Nr.: DE 811835490

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



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

Datum 28.05.2015

Benannte Stelle

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

Date 28.05.2015

Notified Body

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

ARDL CHEMOTHERAPY GLOVES ASTM D6978 Certification



Testing. Development. Problem Solving.

April 10, 2018

• TEST REPORT •

PN 140485

PHARMACEUTICAL SERVICES

Prepared For:

Blake Ma
Hebei Titans Hongsen Medical Technology Co., Ltd.
The Eastern Industrial Accumulation Area Nangong,
Xingtai City Hebei, 055750
China

Prepared By:


Tiffany L. Heller
Assistant Manager, Pharmaceutical Services

Approved By:


Ana C. Barbur, M.S.
Vice President, Analytical & Chemical Services



An A2LA ISO 17025 Accredited Testing Laboratory — Certificate Numbers 255.01 & 255.02
ISO 9001:2008 Registered

ISO 9001:2008
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April 10, 2018

Hebei Titans Hongsen Medical Technology Co., Ltd.

Page 1 of 6 – PN 140485

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; Expiration 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 (Cytosan), 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 cm ²
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 (Cytosan), 20.0 mg/ml (20,000ppm)	200
Cytarabine, 100 mg/ml (100,000 ppm)	272
Cytovene (Ganciclovir), 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
Trisoxex	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) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	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 (Cytosan), 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) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	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
Assistant Manager
Pharmaceutical Services

AKRON RUBBER DEVELOPMENT LABORATORY, INC.



Ana C. Barbur, M.S.,
Vice President
Analytical & Chemical Services

FDA CERTIFICATE OF FACILITY

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=163704>

FEI NUMBER: 3010582952

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HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD
Eastern Industrial Accumulation Area,
Nangong
Xingtai Hebei, CN 051800
Registration Number: 3010582952
FEI Number*: 3010582952
Status: Active
Date Of Registration Status: 2020

Owner/Operator:
HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD
Eastern Industrial Accumulation Area,
Nangong
Xingtai, Hebei CN 051800
Owner/Operator Number: 10045284

Official Correspondent:
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Xingtai, Hebei CN 051800
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or **Business Trade Name** : *hebei titans*
Establishment Registration or FEI Number :
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New Search

Establishment Name		Registration Number	Current Registration Yr
HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD	CHINA	3010582952	2020
Polymer Patient Examination Glove - Powder Free Nitrile Patient Examination Gloves, Blue Color (Brand Name: Titanfine) Contract Manufacturer; Manufacturer Surgeon's Gloves - Powder Free Latex Surgical Gloves, White Color (Brand Name: Titanfine) Contract Manufacturer; Manufacturer Surgeon's Gloves - Powder Free Nitrile Surgical Gloves, White Color (Brand Name: Titanfine) Contract Manufacturer; Manufacturer Polymer Patient Examination Glove - Powder Free Nitrile Gloves (Black); Powder Free Nitrile Gloves (Cobalt Blue); Powder Free Nitrile Gloves (Ice Blue); Powder Free Nitrile Gloves (White) Contract Manufacturer; Manufacturer Polymer Patient Examination Glove - POWDER FREE Blue Nitrile GLOVES, Tested For Use With Chemotherapy Drugs Manufacturer Patient Examination Glove, Specialty - POWDER FREE Blue Nitrile GLOVES, Tested For Use With Chemotherapy Drugs Manufacturer Polymer Patient Examination Glove - Polymer Patient Examination Glove Contract Manufacturer; Manufacturer Polymer Patient Examination Glove - Powder Free Blue Nitrile Examination Gloves, Tested For Use With Chemotherapy Drugs Contract Manufacturer; Manufacturer Patient Examination Glove, Specialty - Powder Free Blue Nitrile Examination Gloves, Tested For Use With Chemotherapy Drugs Contract Manufacturer; Manufacturer Face Mask (Except N95 Respirator) For General Public/Healthcare Personnel Per Iie Guidance - Face Mask Manufacturer			

FDA CERTIFICATE WITH 510K REGISTRATION NUMBER

- Chemotherapy Gloves www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.htm?ID=K181130

New Search	Back To Search Results
Device Classification Name	Patient Examination Glove, Specialty
510(K) Number	K181130
Device Name	Powder Free Blue Nitrile Examination Gloves, Tested For Use With Chemotherapy Drugs
Applicant	Hebei Titans Hongsen Medical Technology Co., LTD. Eastern Industrial Zone Nangong, CN 051800
Applicant Contact	Shaozhang Nan
Correspondent	Beijing Believe-Med Technology Services Co., Ltd. Rm. 912, Building #15, XiYueHui, No.5, YiHe North Rd. FangShan District Beijing, CN 102401
Correspondent Contact	Ray Wang
Regulation Number	880.6250
Classification Product Code	LZC
Subsequent Product Code	LZA
Date Received	04/30/2018
Decision Date	08/10/2018
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Predicate Device: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.htm?ID=k163146>

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.

New Search	Back To Search Results
Device Classification Name	Patient Examination Glove, Specialty
510(K) Number	K163146
Device Name	POWDER FREE Blue Nitrile GLOVES, Tested For Use With Chemotherapy Drugs
Applicant	HEBEI HONGSEN PLASTICS TECHNOLOGY CO, LTD ESTERN INDUSTRIAL ZONE Nangong, CN 051800
Applicant Contact	Shaozhang Nan
Correspondent	BEIJING BELIEVE TECH. SERVICE CO., LTD. 5-1206, BUILD 332, DAFANGJU, NO.25 BANBIDIAN RD.,LIYUAN, TONGZHOU DISTRICT Beijing, CN 101121
Correspondent Contact	Ray Wang
Regulation Number	880.6250
Classification Product Code	LZC
Subsequent Product Code	LZA
Date Received	11/09/2016
Decision Date	02/13/2017
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

- **Powder Free Nitrile Patient Examination Gloves**

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=k163553>

Device Classification Name	Polymer Patient Examination Glove
510(K) Number	K163553
Device Name	Powder Free Nitrile Patient Examination Gloves, Blue
Applicant	HEBEI TITANS MEDICAL SUPPLY TECHNOLOGY GROUP.,LTD. EAST OF JINGQIANG COMMUNITY, DAQING ST, XINGTAI Nangong, CN 051800
Applicant Contact	Shaozhang Nan
Correspondent	Beijing Believe Tech. Service Co., Ltd. 5-1206, Build 332, DaFangJu, No.25 BanBiDian Rd., TongZhou District Beijing, CN
Correspondent Contact	Ray Wang
Regulation Number	880.6250
Classification Product Code	LZA
Date Received	12/19/2016
Decision Date	05/22/2017
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Predicate Device: Powder Free Nitrile Patient Examination Gloves

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=k131440>

Device Classification Name	Polymer Patient Examination Glove
510(K) Number	K131440
Device Name	POWDER FREE NITRILE PATIENT EXAMINATION GLOVES, BLUE
Applicant	HEBEI HONGSEN PLASTICS TECHNOLOGY CO, LTD 5 CAREY STREET Pennington, NJ 08534
Applicant Contact	Charles Shen
Correspondent	HEBEI HONGSEN PLASTICS TECHNOLOGY CO, LTD 5 CAREY STREET Pennington, NJ 08534
Correspondent Contact	Charles Shen
Regulation Number	880.6250
Classification Product Code	LZA
Date Received	05/20/2013
Decision Date	09/25/2013
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	Yes

6.1 FDA 510K NO.: K181130: Powder Free Nitrile Examination Gloves, Tested for use with Chemotherapy Drugs



FDA U.S. FOOD & DRUG
ADMINISTRATION

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 -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

Indications for Use

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 HCl	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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@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."

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, LZA

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		
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(Cytosan)	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 HCl	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(Cytosan), Cytarabine, Cytovene, Dacarbazine(DTIC) , Daunorubicin, Docetaxel, Doxorubicin, Hydrochloride, Ellence, toposide(Toposar), Fludarabine, Fluorouracil, Gemcitabine (Gemzar), Idarubicin, Ifosfamide, Irinotecan, Mechlorethamine HCl, Melphalan, Methotrexate, Mitomycin C, Mitoxantrone, Oxaliplatin, Paclitaxel (Taxol), Rituximab, Thiotepa, Trisenox, Vincristine Sulfate, Vinorelbine	Fluorouracil, Etoposide (Toposar), Cyclophosphamid (Cytosan), 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.

6.2 FDA 510K NO.: K163553 Powder Free Nitrile Patient Examination Gloves, Blue



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](#).

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,

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

Indications for Use

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.

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Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

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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
Predicate Device (k131440) Powder free Patient Examination Gloves, Blue Color	Cuff	0.06					±0.03
	Designation	Size					Tolerance
		XS	S	M	L	XL	
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-4 Safety 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.

CE CERTIFICATE

Certificate No. AK 60090940

Certificate Holder:	Hebei Titans Hongsen Medical Technology Co., Ltd. Eastern Industrial Zone Nangong City, Xingtai City 051800 Hebei China (Mainland)
Certificate Number:	AK 60090940
Order Number:	3091541
Certified Product:	Gloves (medizinische Einmalhandschuhe) Model Designation: Titanfine
Fulfilled Standards:	EN 455-1:2000 EN 455-3:2006 The standard(s) listed here reflect the status at the time of the release of this certificate.
Date of Issue:	2013-12-19
Certificate Type:	Certificate of Conformity The certificate of conformity (CoC) refers to the product specified in the certificate. The certificate demonstrates that a product sample was tested and evaluated at a specific time, and found to be in conformity with the assessment requirements specified in the certificate. A CoC is relevant to importers and exporters to prove that products comply with local regulations. This certificate does not imply an assessment of the product's production and does not permit the use of a TÜV Rheinland test mark.

Further Information

- Request more information on Hebei Titans Hongsen Medical Technology Co., Ltd.
- All product certificates of Hebei Titans Hongsen Medical Technology Co., Ltd.
- All certified management systems of Hebei Titans Hongsen Medical Technology Co., Ltd.

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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TECHNICAL PRODUCT TESTING REPORTS



Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Mr. Wenxin Lu
Hebei Hongsen Plastics
Technology Co., Ltd.
Eastern Industrial Accumulation Zone
051800 NANGONG CITY, HEBEI
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
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

Dipl.-Ing. C. Albrecht

Test sample: stored by warehouse Leipzig

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

Board of Management

Dipl.-Ing.
Jörg Mahler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nürnberg HRB 26013
UST-ID Nr.: DE 811635490

Prüfbericht-Nr.: <i>Test Report No.:</i>	21231212_001	Auftrags-Nr.: <i>Order No.:</i>	3137466	Seite 1 von 15 Page 1 of 15
Kunden-Referenz-Nr.: <i>Client Reference No.:</i>	Ord. 1140017489	Auftragsdatum: <i>Order date:</i>	03.02.2015	
Auftraggeber: <i>Client:</i>	Hebei Hongsen Plastics Technology Co., Ltd. Eastern Industrial zone, Nangong City, Hebei, P.R. China			
Prüfgegenstand: <i>Test item:</i>	Schutzhandschuhe / Protective gloves			
Bezeichnung / Typ-Nr.: <i>Identification / Type No.:</i>	Nitrilhandschuhe (12 inch, blau) / nitrile gloves (12 inches, blue) TITANFINE REF HS6213, HS6214, HS6215, HS6216, HS6217			
Auftrags-Inhalt: <i>Order content:</i>	Baumusterprüfung / EC Type Approval			
Prüfgrundlage: <i>Test specification:</i>	EN 374-1:2003, EN 374-2:2003, EN 374-3:2003 Schutzhandschuhe gegen Chemikalien und Mikroorganismen <i>Protective gloves against chemicals and micro-organisms</i>			
Wareneingangsdatum: <i>Date of receipt:</i>	23.02.2015			
Prüfmuster-Nr.: <i>Test sample No.:</i>	A*91054			
Prüfzeitraum: <i>Testing period:</i>	27.02.2015 – 06.05.2015			
Ort der Prüfung: <i>Place of testing:</i>	Prüfstelle für Textilien und PSA Leipzig			
Prüflaboratorium: <i>Testing laboratory:</i>	TÜV Rheinland LGA Products GmbH			
Prüfergebnis*: <i>Test result*:</i>	Pass			
geprüft von / tested by:		kontrolliert von / reviewed by:		
07.05.2015	J. Voigt / Sachverständige/Expert	07.05.2015	M. Schultz / Sachverständiger/Expert	
Datum <i>Date</i>	Name / Stellung <i>Name / Position</i>	Unterschrift <i>Signature</i>	Datum <i>Date</i>	Name / Stellung <i>Name / Position</i>
				Unterschrift <i>Signature</i>
Sonstiges / Other:				
Zustand des Prüfgegenstandes bei Anlieferung: <i>Condition of the test item at delivery:</i>		Prüfmuster vollständig und unbeschädigt <i>Test item complete and undamaged</i>		
* 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				
Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens. <i>This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.</i>				

[illegible]

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Produktbeschreibung
Product description

1	Produktdetails <i>Product details</i>	5-Finger-Handschuh <i>5 finger gloves</i>
2	Artikel / Modell <i>Article / Model</i>	Nitrilhandschuhe (12 inch, blau) / <i>nitrile gloves (12 inches, blue)</i> TITANFINE REF HS6213, HS6214, HS6215, HS6216, HS6217
3	Größe / Länge <i>Size / Length</i>	XS, S, M, L, XL
4	Leistungsstufen <i>Performance levels</i>	chemisch/ <i>chemical</i> (I) Ethyl acetate 0 (K) NaOH 40% 6 (L) H₂SO₄ 96% 1 mechanisch/ <i>mechanical</i>: 1 0 0 1
5	Verwendete Materialien <i>Used materials</i>	Nitril / <i>nitrile</i>
6	Chargennr. <i>Charge no.</i>	---
7	Sonstiges <i>Other</i>	Vorhersehbare Verwendung wurde betrachtet. Zurzeit liegen für das/die Produkt/e weder Schutzklauselverfahren an, noch ist ein erhöhtes Unfallaufkommen bekannt. <i>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).</i>
8	Mitgeltende Dokumente / Prüfberichte <i>Further applicable documents / test reports</i>	Prüfbericht Permeation / <i>Test report permeation</i> Bericht-Nr. / <i>report nr.</i>: AZ196659 (17.03.2015)
Nitrile glove, 12 inches, blue, powder free		
		

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

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Clause	Anforderungen - Prüfungen / Requirements - Tests	Measuring results - Remarks		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. <i>The pH value for all gloves shall be greater than 3,5 and less than 9,5.</i>	Innenhand Palm	pH-Wert pH- value 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. <i>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.</i>	---		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) <i>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)</i>	---		P ☐ F ☐ N/A ☒ N/T ☐

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Clause	Anforderungen - Prüfungen / <i>Requirements - Tests</i>			<i>Measuring results - Remarks</i>	<i>Evaluation</i>

EN 420 4.4	Reinigung <i>Cleaning</i>																																													
	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. <i>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.</i>	---	P ☐ F ☐ N/A ☒ N/T ☐																																											
EN 420 4.5	Elektrostatische Eigenschaften <i>Electrostatic properties</i>																																													
	wenn erforderlich/ <i>if required</i> : 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. <i>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.</i>	---	P ☐ F ☐ N/A ☒ N/T ☐																																											
EN 420 5	Komfort und Leistungsfähigkeit <i>Comfort and efficiency</i>																																													
EN 420 5.1	Größen <i>Sizing</i>																																													
EN 420 5.1.2	Größen und Maße der Handschuhe <i>Sizes and measurements of glove</i>																																													
Tab. 2, Tab. 3	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 10%;">Handschuhgröße <i>Glove size</i></th> <th style="width: 15%;">Handumfang <i>Hand circumference</i> [mm]</th> <th style="width: 15%;">Handlänge <i>Hand length</i> [mm]</th> <th style="width: 20%;">Mindestlänge des Handschuhs <i>Minimum length of glove</i> [mm]</th> </tr> </thead> <tbody> <tr><td>6</td><td>152</td><td>160</td><td>220</td></tr> <tr><td>7</td><td>178</td><td>171</td><td>230</td></tr> <tr><td>8</td><td>203</td><td>182</td><td>240</td></tr> <tr><td>9</td><td>229</td><td>192</td><td>250</td></tr> <tr><td>10</td><td>254</td><td>204</td><td>260</td></tr> <tr><td>11</td><td>279</td><td>215</td><td>270</td></tr> </tbody> </table>	Handschuhgröße <i>Glove size</i>	Handumfang <i>Hand circumference</i> [mm]	Handlänge <i>Hand length</i> [mm]	Mindestlänge des Handschuhs <i>Minimum length of glove</i> [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	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 15%;">Größe <i>Size</i></th> <th style="width: 35%;">Handschuhlänge <i>Glove length</i> [mm]</th> </tr> </thead> <tbody> <tr><td>6</td><td>298</td></tr> <tr><td>7</td><td>300</td></tr> <tr><td>8</td><td>301</td></tr> <tr><td>9</td><td>299</td></tr> <tr><td>10</td><td>305</td></tr> <tr><td>11</td><td>---</td></tr> </tbody> </table>	Größe <i>Size</i>	Handschuhlänge <i>Glove length</i> [mm]	6	298	7	300	8	301	9	299	10	305	11	---	P ☒ F ☐ N/A ☐ N/T ☐	
Handschuhgröße <i>Glove size</i>	Handumfang <i>Hand circumference</i> [mm]	Handlänge <i>Hand length</i> [mm]	Mindestlänge des Handschuhs <i>Minimum length of glove</i> [mm]																																											
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Clause	Anforderungen - Prüfungen / Requirements - Tests		Measuring results - Remarks	Evaluation											
EN 420 5.1.3	Handschuhe für besondere Anwendungen <i>Gloves for special applications</i>														
	für den speziellen Zweck passend (eindeutig angegeben in der Gebrauchsanweisung) <i>fit for special purpose</i> <i>(clearly stated in instruction for use)</i>	---	P ☐ F ☐ N/A ☒ N/T ☐												
EN 420 5.2	Beweglichkeit <i>Dexterity</i>														
Tab. 4	<table><tr><th>Leistungsstufe Performance level</th><th>geringster Durchmesser des Stiftes <i>smallest diameter of pin</i> [mm]</th></tr><tr><td>1</td><td>11</td></tr><tr><td>2</td><td>9,5</td></tr><tr><td>3</td><td>8</td></tr><tr><td>4</td><td>6,5</td></tr><tr><td>5</td><td>5</td></tr></table>	Leistungsstufe Performance level	geringster Durchmesser des Stiftes <i>smallest diameter of pin</i> [mm]	1	11	2	9,5	3	8	4	6,5	5	5	Prüfstift / <i>pin</i> : 5 mm	P ☒ F ☐ N/A ☐ N/T ☐ Stufe / <i>Level 5</i>
Leistungsstufe Performance level	geringster Durchmesser des Stiftes <i>smallest diameter of pin</i> [mm]														
1	11														
2	9,5														
3	8														
4	6,5														
5	5														
EN 420 5.3	Wasserdampfdurchlässigkeit (WDD) und Wasserdampfaufnahme (WDA) <i>Water vapour transmission (WVT) and Water vapour absorption (WVA)</i>														
EN 420 5.3.1	sofern durchführbar, müssen Schutzhandschuhe wasserdampfdurchlässig sein sofern gefordert: WDD ≥ 5 mg/ (cm²h) <i>protective gloves shall allow water vapour transmission.</i> <i>if required: WVT: ≥ 5 mg/ (cm².h)</i>	---	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 <i>where protection level inhibits or excludes water vapour</i> <i>transmission, effect of perspiration has to be reduced</i> <i>if required: WVA: ≥ 8 mg/cm² for 8 h</i>	---	P ☐ F ☐ N/A ☒ N/T ☐												
2	Normative Verweisungen <i>Normative references</i>														
3	Begriffe <i>Terms and definition</i>														

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4	Prüfverfahren Method of testing																										
	Ausführliche Prüfverfahren werden in folgenden Teilen dieser Norm angegeben / <i>detailed test methods will be found in the following parts of this standard:</i> 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. <i>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.</i>																										
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. <i>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.</i>																										
Tab. A1	<table border="1"> <thead> <tr> <th>Leistungsstufe / performance level</th><th>Annehmbare Qualitätsrenzlage / acceptable quality level / unit</th><th>Prüfniveau / Inspection levels</th></tr> </thead> <tbody> <tr> <td>Niveau / level 3</td><td>< 0,65</td><td>G1</td></tr> <tr> <td>Niveau / level 2</td><td>< 1,5</td><td>G1</td></tr> <tr> <td>Niveau / level 1</td><td>< 4,0</td><td>S4</td></tr> </tbody> </table> Luft-Leck-Prüfung / <i>Air leakage</i> Wasser-Leck-Prüfung / <i>Water leakage</i>	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	geprüfte Menge/ <i>tested quantity:</i> 10 Stück/pieces akzeptierte Fehler/ <i>accepted defects:</i> 0 Stück/pieces Luft-Leck-Prüfung / <i>Air leakage</i> <table border="1"> <tr> <td></td><td>dicht/ not leaking</td><td>undicht/ leaking</td></tr> <tr> <td></td><td>10</td><td>0</td></tr> </table> Wasser-Leck-Prüfung / <i>Water leakage</i> <table border="1"> <tr> <td></td><td>dicht/ not leaking</td><td>undicht/ leaking</td></tr> <tr> <td></td><td>10</td><td>0</td></tr> </table>		dicht/ not leaking	undicht/ leaking		10	0		dicht/ not leaking	undicht/ leaking		10	0	P ☒ F ☐ N/A ☐ N/T ☐
Leistungsstufe / performance level	Annehmbare Qualitätsrenzlage / acceptable quality level / unit	Prüfniveau / Inspection levels																									
Niveau / level 3	< 0,65	G1																									
Niveau / level 2	< 1,5	G1																									
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5.3	Permeation <i>Permeation</i>
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 <i>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</i>
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. <i>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.</i>

Anhang A/ <i>Annex A</i>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 15%; padding: 5px;">Kennbuchstabe <i>Code letter</i></th> <th style="padding: 5px;">Prüfchemikalien <i>Chemical</i></th> </tr> <tr><td style="text-align: center;">A</td><td>Methanol / <i>Methanol</i></td></tr> <tr><td style="text-align: center;">B</td><td>Aceton / <i>Acetone</i></td></tr> <tr><td style="text-align: center;">C</td><td>Acetonitril / <i>Acetonitrile</i></td></tr> <tr><td style="text-align: center;">D</td><td>Dichloromethan / <i>Dichloromethane</i></td></tr> <tr><td style="text-align: center;">E</td><td>Kohlenstoffdisulfid / <i>Carbon disulphide</i></td></tr> <tr><td style="text-align: center;">F</td><td>Toluol / <i>Toluene</i></td></tr> <tr><td style="text-align: center;">G</td><td>Diethylamin / <i>Diethylamine</i></td></tr> <tr><td style="text-align: center;">H</td><td>Tetrahydrofuran / <i>Tetrahydrofurane</i></td></tr> <tr><td style="text-align: center;">I</td><td>Ethylacetat / <i>Ethyl acetate</i></td></tr> <tr><td style="text-align: center;">J</td><td>n-Heptan / <i>n-Heptane</i></td></tr> <tr><td style="text-align: center;">K</td><td>Natriumhydroxid 40 % / <i>Sodium hydroxide 40 %</i></td></tr> <tr><td style="text-align: center;">L</td><td>Schwefelsäure 96 % / <i>Sulphuric acid 96 %</i></td></tr> </table>	Kennbuchstabe <i>Code letter</i>	Prüfchemikalien <i>Chemical</i>	A	Methanol / <i>Methanol</i>	B	Aceton / <i>Acetone</i>	C	Acetonitril / <i>Acetonitrile</i>	D	Dichloromethan / <i>Dichloromethane</i>	E	Kohlenstoffdisulfid / <i>Carbon disulphide</i>	F	Toluol / <i>Toluene</i>	G	Diethylamin / <i>Diethylamine</i>	H	Tetrahydrofuran / <i>Tetrahydrofurane</i>	I	Ethylacetat / <i>Ethyl acetate</i>	J	n-Heptan / <i>n-Heptane</i>	K	Natriumhydroxid 40 % / <i>Sodium hydroxide 40 %</i>	L	Schwefelsäure 96 % / <i>Sulphuric acid 96 %</i>
Kennbuchstabe <i>Code letter</i>	Prüfchemikalien <i>Chemical</i>																										
A	Methanol / <i>Methanol</i>																										
B	Aceton / <i>Acetone</i>																										
C	Acetonitril / <i>Acetonitrile</i>																										
D	Dichloromethan / <i>Dichloromethane</i>																										
E	Kohlenstoffdisulfid / <i>Carbon disulphide</i>																										
F	Toluol / <i>Toluene</i>																										
G	Diethylamin / <i>Diethylamine</i>																										
H	Tetrahydrofuran / <i>Tetrahydrofurane</i>																										
I	Ethylacetat / <i>Ethyl acetate</i>																										
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K	Natriumhydroxid 40 % / <i>Sodium hydroxide 40 %</i>																										
L	Schwefelsäure 96 % / <i>Sulphuric acid 96 %</i>																										

Tab. 1	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 25%; padding: 5px;">Durchbruchzeit / <i>Measured breakthrough time</i> [min]</th> <th style="width: 25%; padding: 5px;">Schutzindex / <i>Permeation performance level</i></th> </tr> <tr><td style="text-align: center;">> 10</td><td>Klasse / <i>class</i> 1</td></tr> <tr><td style="text-align: center;">> 30</td><td>Klasse / <i>class</i> 2</td></tr> <tr><td style="text-align: center;">> 60</td><td>Klasse / <i>class</i> 3</td></tr> <tr><td style="text-align: center;">> 120</td><td>Klasse / <i>class</i> 4</td></tr> <tr><td style="text-align: center;">> 240</td><td>Klasse / <i>class</i> 5</td></tr> <tr><td style="text-align: center;">> 480</td><td>Klasse / <i>class</i> 6</td></tr> </table>	Durchbruchzeit / <i>Measured breakthrough time</i> [min]	Schutzindex / <i>Permeation performance level</i>	> 10	Klasse / <i>class</i> 1	> 30	Klasse / <i>class</i> 2	> 60	Klasse / <i>class</i> 3	> 120	Klasse / <i>class</i> 4	> 240	Klasse / <i>class</i> 5	> 480	Klasse / <i>class</i> 6	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 25%; padding: 5px;">Prüf- chemikalie / <i>Chemical</i></th> <th style="width: 25%; padding: 5px;">Durchbruchzeit / <i>Measured breakthrough time</i> [min]</th> <th style="width: 50%;"></th> </tr> <tr> <td style="text-align: center;">Ethyl acetate</td> <td style="text-align: center;">0</td> <td rowspan="3" style="vertical-align: middle;"> Level 0 Level 6 Level 1 </td> </tr> <tr> <td style="text-align: center;">NaOH 40%</td> <td style="text-align: center;">>480</td> </tr> <tr> <td style="text-align: center;">H₂SO₄ 96%</td> <td style="text-align: center;">22</td> </tr> <tr> <td colspan="2" style="padding: 5px;">Schutz gegen geringe chemische Risiken/ <i>protection against low chemical risks</i></td> <td></td> </tr> </table>	Prüf- chemikalie / <i>Chemical</i>	Durchbruchzeit / <i>Measured breakthrough time</i> [min]		Ethyl acetate	0	Level 0 Level 6 Level 1	NaOH 40%	>480	H ₂ SO ₄ 96%	22	Schutz gegen geringe chemische Risiken/ <i>protection against low chemical risks</i>		
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NaOH 40%	>480																												
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Schutz gegen geringe chemische Risiken/ <i>protection against low chemical risks</i>																													

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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	<table><tr><th>Leistungsstufe Performance level</th><th>Abriebfestigkeit [Zyklen] Abrasion [cycles]</th></tr><tr><td>1</td><td>100</td></tr><tr><td>2</td><td>500</td></tr><tr><td>3</td><td>2000</td></tr><tr><td>4</td><td>8000</td></tr></table>	Leistungsstufe Performance level	Abriebfestigkeit [Zyklen] Abrasion [cycles]	1	100	2	500	3	2000	4	8000	Durchbruch bei ca. [Zyklen] Breaktrough at about [cycles] <table><tr><th>1. Lage / layer</th><th>2. Lage / layer</th></tr><tr><td>100-500</td><td>---</td></tr><tr><td>500-2000</td><td>---</td></tr><tr><td>500-2000</td><td>---</td></tr><tr><td>500-2000</td><td>---</td></tr></table>	1. Lage / layer	2. Lage / layer	100-500	---	500-2000	---	500-2000	---	500-2000	---	<table><tr><td>P</td><td>☒</td></tr><tr><td>F</td><td>☐</td></tr><tr><td>N/A</td><td>☐</td></tr><tr><td>N/T</td><td>☐</td></tr></table>	P	☒	F	☐	N/A	☐	N/T	☐
	Leistungsstufe Performance level	Abriebfestigkeit [Zyklen] Abrasion [cycles]																													
	1	100																													
	2	500																													
	3	2000																													
	4	8000																													
1. Lage / layer	2. Lage / layer																														
100-500	---																														
500-2000	---																														
500-2000	---																														
500-2000	---																														
P	☒																														
F	☐																														
N/A	☐																														
N/T	☐																														
	Schleifpapier / abrasive paper: Klingspor PL31B Gritt 180	niedrigster Wert zur Klassifizierung / lowest value for classification: 100	Stufe / level 1																												

EN 388 6.2 Schnittfestigkeit
Blade cut resistance

Tab. 1

Leistungsstufe <i>Performance level</i>	Schnittfestigkeit [Faktor] <i>Blade cut resistance [Factor]</i>
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

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

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Clause	Anforderungen - Prüfungen / Requirements - Tests		Measuring results - Remarks	Evaluation																													
EN 388 6.3	Weiterreißfestigkeit Tear resistance																																
Tab. 1	<table><tr><th>Leistungsstufe Performance level</th><th>Weiterreißfestigkeit [N] Tear resistance [N]</th></tr><tr><td>1</td><td>10</td></tr><tr><td>2</td><td>25</td></tr><tr><td>3</td><td>50</td></tr><tr><td>4</td><td>75</td></tr></table>	Leistungsstufe Performance level	Weiterreißfestigkeit [N] Tear resistance [N]	1	10	2	25	3	50	4	75	<table><tr><th colspan="2">Einzelwerte [N] Several values [N]</th></tr><tr><th>1. Lage / layer</th><th>2. Lage / layer</th></tr><tr><td>1,78</td><td>---</td></tr><tr><td>1,97</td><td>---</td></tr><tr><td>1,92</td><td>---</td></tr><tr><td>1,67</td><td>---</td></tr></table> niedrigster Wert zur Klassifizierung / lowest value for classification: 1,67 N	Einzelwerte [N] Several values [N]		1. Lage / layer	2. Lage / layer	1,78	---	1,97	---	1,92	---	1,67	---	<table><tr><td>P</td><td>☐</td></tr><tr><td>F</td><td>☐</td></tr><tr><td>N/A</td><td>☒</td></tr><tr><td>N/T</td><td>☐</td></tr></table> Stufe / level 0	P	☐	F	☐	N/A	☒	N/T	☐
Leistungsstufe Performance level	Weiterreißfestigkeit [N] Tear resistance [N]																																
1	10																																
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P	☐																																
F	☐																																
N/A	☒																																
N/T	☐																																
EN 388 6.4	Durchstichfestigkeit Puncture resistance																																
Tab. 1	<table><tr><th>Leistungsstufe Performance level</th><th>Durchstichfestigkeit [N] Puncture resistance [N]</th></tr><tr><td>1</td><td>20</td></tr><tr><td>2</td><td>60</td></tr><tr><td>3</td><td>100</td></tr><tr><td>4</td><td>150</td></tr></table>	Leistungsstufe Performance level	Durchstichfestigkeit [N] Puncture resistance [N]	1	20	2	60	3	100	4	150	<table><tr><th colspan="2">Einzelwerte [N] several values [N]</th></tr><tr><td>21,22</td><td>27,88</td></tr><tr><td>26,88</td><td>26,20</td></tr></table> niedrigster Wert zur Klassifizierung / lowest value for classification: 21,22 N	Einzelwerte [N] several values [N]		21,22	27,88	26,88	26,20	<table><tr><td>P</td><td>☒</td></tr><tr><td>F</td><td>☐</td></tr><tr><td>N/A</td><td>☐</td></tr><tr><td>N/T</td><td>☐</td></tr></table> Stufe / level 1	P	☒	F	☐	N/A	☐	N/T	☐						
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																																
P	☒																																
F	☐																																
N/A	☐																																
N/T	☐																																
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. <i>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.</i>																																
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. <i>All details have to be precise and in official language of country of destination.</i>	gegeben given	<table><tr><td>P</td><td>☒</td></tr><tr><td>F</td><td>☐</td></tr><tr><td>N/A</td><td>☐</td></tr><tr><td>N/T</td><td>☐</td></tr></table>	P	☒	F	☐	N/A	☐	N/T	☐																						
P	☒																																
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EN 420 7.2	Kennzeichnung und Information – Kennzeichnung <i>Marking and Information – Marking</i>		
EN 420 7.2.1	Jeder Schutzhandschuh muss mit folgenden Angaben gekennzeichnet sein: - Name, Handelsmarke oder andere Erkennungsmerkmale 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 <i>Each protective glove shall be marked with the following information:</i> - 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 <i>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</i>	P ☒ F ☐ N/A ☐ N/T ☐
	für Schutzhandschuhe, die die Anforderungen an Penetration und Permeation erfüllen – Piktogramm für chemische Gefahren <i>for gloves complying to the requirements for penetration and permeation – chemical pictogram:</i>  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 / <i>for gloves complying to the requirement for penetration – pictogram for waterproof gloves with low chemical protection</i> 	gegeben <i>given</i>	P ☒ F ☐ N/A ☐ N/T ☐

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EN 420 7.2.2	Kennzeichnung und Information – Kennzeichnung der Verpackung <i>Marking and Information – Marking of Packaging</i> Jede kleinste Verpackungseinheit, welche den Handschuh unmittelbar enthält, muss eindeutig mit den nachfolgenden Angaben gekennzeichnet sein: - Name und volle Anschrift des Herstellers oder seines autorisierten 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 - Hinweis, wo die Information des Herstellers zu erhalten ist - bei einfachen Handschuhen der Hinweis, „Nur bei minimalen Gefahren“ o. ä. - das Piktogramm mit der Nummer der Norm und die Leistungsstufen - CE-Zeichen gemäß Richtlinie 89/686/EWG <i>Each packaging enclosure that immediately contains the gloves shall be clearly marked with the following:</i> - 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 - Note where the information of the manufacturer is to obtain - for simple gloves note "Only for minimal risks" etc. - Pictogram with number of standard and performance levels - CE-mark in accordance to Directive 89/686/EEC		
	Hebei Hongsen Plastics Technology Co., Ltd. Titanfine REF HS6213, HS6214, HS6215, HS6216, HS6217 z.B. M Platzhalter gegeben N/A gegeben gegeben	P ☒ F ☐ N/A ☐ N/T ☐	
	Hebei Hongsen Plastics Technology Co., Ltd. Titanfine REF HS6213, HS6214, HS6215, HS6216, HS6217 e.g. M placeholder given gegeben N/A given given		

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7	Information des Herstellers Information supplied by the manufacturer		
	Informationen des Herstellers müssen den Anforderungen in EN 420 entsprechen. <i>The information supplied by the manufacturer shall be in accordance with the requirements for information as defined in EN 420.</i>		
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 <i>The following minimum information shall be supplied:</i> - 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 ☐

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	Zusatzinformationen: - Einzelheiten zu besonderen Prüfungen, die unter anderen klimatischen Bedingungen durchgeführt wurden, müssen angegeben werden - 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 - Ein Warnhinweis muss enthalten sein, dass in Fällen, bei denen ein Risiko besteht, sich in bewegten Maschinenteilen zu verfangen, keine Handschuhe getragen werden sollten - 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. - Die Informationen müssen einen Warnhinweis enthalten, dass durch die Angabe des Schutzindex keine Aussage gemacht wird über die tatsächliche Schutzdauer am Arbeitsplatz, da weitere Faktoren wie Temperatur, Abrieb usw. die Gebrauchstauglichkeit beeinflussen. - Die Leistungsstufe und die annehmbare Qualitätsgrenzlage (AQL) für die Prüfung der Penetration in der Produktion sind anzugeben. Additional information: - details of any special tests carried out in a different environment shall be given - 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 - users should be warned that gloves should not be worn when there is a risk of entanglement by moving parts of machines - 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. - 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. - The level of performance and associated AQL for penetration production control shall be reported.	N/A N/A gegeben gegeben gegeben N/A N/A N/A given given given N/A	P ☒ F ☐ N/A ☐ N/T ☐

END OF DOCUMENT