

Founded in 2010, Titans group is specialized in research, manufacture, sale and service. With registered capital of 200 million yuan and as one of the larger production enterprises of disposable protective equipment in the world, Titans group has independent import and export right and its annual export volume is over \$100000000. **At present, the group has 4 subsidiaries respectively in Shijiazhuang, Xingtainangong(Hebei Hongsen Plastics Technology Co., Ltd.)and Pingshan(Super Safe Plastic Products Co., Ltd.), Hebei Province**, with main products of disposable protective equipment including nitrile gloves, nitrile cleanroom gloves, latex gloves, Vinyl gloves, PE products, mask and other Nonwoven products. Further, products could be classified, in terms of grade, as clean grade (clean-series-class 10, class 100 and class 1000) , medical grade (category I and category II) and non-medical grade. Gloves could be powdered, powder-free, lengthened, thickened, ultra-light and ultra-thin in various of color and type. The group has six utility model patent and its products are exported to more than 40 countries and regions such as Japan, the Middle East, America and EU Member States, at the same time winning recognition at home. With all of its employees adhering to the principles of “quality and innovation first” and “pursuit of excellence and best customer service”, Titans group is in line with the international advanced level in production scale, technical equipment, technical level and product quality and it is ISO9001:2008 (quality management system certification) , ISO 13485:2003 (medical equipment quality management system certification) , America FDA510K and Eu CE (89/68 / EEC, 93/42 / EEC and etc.) certified. We are sincerely expecting for building cooperation and friendship with new and old customers by honesty and hard work. We will try to meet your need by adopting more rigorous scientific management mode and excellent production process.











 **Titanfine<sup>®</sup>**



2 FT

**SINGLE-USE  
NITRILE GLOVES**

  
100







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## **Nitrile9"4.0g blue**

Color: Nitrile9"4.0g blue

TypeOfPitting: finger-textured, fully texture and etc.

Version: XS/S/M/L/XL

Pinhole: medical grade: AQL1.0/1.5, industrial grade: AQL4.0

Surface: medical grade: AQL1.5, industrial grade: AQL4.0

Packaging: 100pcs/ box, 10boxes/case





证书编号: 2013100106S



**Sanitation & Environment Technology Institute,  
Soochow University,  
Final Report**

Report Number: SDWH-M201404168

Skin Sensitization Test of Ice blue nitrile gloves  
using ISO 10993-10:2010 Test Methods  
Guinea Pig Maximization Test  
0.9% Sodium Chloride Injection Extract

Sponsor

HEBEI HONGSEN PLASTICS TECHNOLOGY CO., LTD.

Sanitation & Environment Technology Institute, Soochow University  
Tel: 0512-65880038 Fax: 0512-65880034 Email: sudaweihuan@163.com PC: 215123  
Add: No.199 Ren'ai Road, Suzhou Industrial Park, China <http://yxbfzb.suda.edu.cn>  
Page 1 of 13

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



# 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.22.2020

Date of expiry: Jan.28.2022

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



## 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

Applied harmonized standards: EN455-1: 2000, EN455-2: 2015, EN455-3: 2015, EN ISO14971:2012, 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.

**CE**

Signature: *Feng Shuangyan*

Date: April 23, 2019

Quality Supervision Organization



## CE technical file audit report

Manufacturer:

Name: Hebei Titans Hongsen Medical Technology Co., Ltd.

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

Purpose of review: Evaluate the conformity of technical documents according to the requirements of EU Medical Device Directive 93/42 / EEC Appendix VII;


Product name and model: Disposable nitrile examination gloves

**XS, S, M, L and XL**

Product category: Class I (Classification according to the medical device directive 93/42 / EEC Appendix IX Part III Part 1.1 / 1.4)

Review results : Passed the technical documentation review of nitrile gloves (Numbering: HS201804010, Revised edition: A, Date: 201804-12). According to the requirements of Annex VII of the Medical Device Directive 93/42 / EEC, no non-compliance was found.

Signature:



Date: April 23, 2019

Regulatory Authority



# 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



# 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 - 90434 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>



**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](mailto:service@de.tuv.com)

Date May 28, 2015

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

Dear Ms. Liu,

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

The license holder is:

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

Kind regards

Certification body



Dipl.-Ing. C. Albrecht

TÜV Rheinland  
LGA Products GmbH

Tillystraße 2  
90431 Nürnberg

Tel. +49 911 655-5225  
Fax +49 911 655-5226  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)  
Web [www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Nürnberg HRB 26013  
UST-ID Nr.: DE 811835490



**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](mailto:service@de.tuv.com)

Date May 28, 2015

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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](mailto:service@de.tuv.com)  
Web [www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Nürnberg HRB 26013  
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



**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 EG-Richtlinien angebracht werden. Ⓒ



**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



**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



|   |   |   |   |  |
|---|---|---|---|--|
| <b>Prüfbericht-Nr.:</b><br><i>Test Report No.:</i>  | <b>21231212_001</b>   | <b>Auftrags-Nr.:</b><br><i>Order No.:</i>   | <b>3137466</b>                              | <b>Seite 1 von 15</b><br><i>Page 1 of 15</i>     |
| <b>Kunden-Referenz-Nr.:</b><br><i>Client Reference No.:</i>   | <b>Ord. 1140017489</b>  | <b>Auftragsdatum:</b><br><i>Order date:</i>   | <b>03.02.2015</b>                           |  |
| <b>Auftraggeber:</b><br><i>Client:</i>  | <b>Hebei Hongsen Plastics Technology Co., Ltd.</b><br>Eastern Industrial zone, Nangong City, Hebei, P.R. China  |   |   |  |
| <b>Prüfgegenstand:</b><br><i>Test item:</i>   | <b>Schutzhandschuhe / Protective gloves</b>   |   |   |  |
| <b>Bezeichnung / Typ-Nr.:</b><br><i>Identification / Type No.:</i>  | <b>Nitrilhandschuhe (12 inch, blau) / nitrile gloves (12 inches, blue)</b><br><b>TITANFINE REF HS6213, HS6214, HS6215, HS6216, HS6217</b>   |   |   |  |
| <b>Auftrags-Inhalt:</b><br><i>Order content:</i>  | <b>Baumusterprüfung / EC Type Approval</b>  |   |   |  |
| <b>Prüfgrundlage:</b><br><i>Test specification:</i>   | <b>EN 374-1:2003, EN 374-2:2003, EN 374-3:2003</b><br><b>Schutzhandschuhe gegen Chemikalien und Mikroorganismen</b><br><b>Protective gloves against chemicals and micro-organisms</b> |   |   |  |
| <b>Wareneingangsdatum:</b><br><i>Date of receipt:</i>   | <b>23.02.2015</b>   |        |   |  |
| <b>Prüfmuster-Nr.:</b><br><i>Test sample No.:</i>   | <b>A*91054</b>  |   |   |  |
| <b>Prüfzeitraum:</b><br><i>Testing period:</i>  | <b>27.02.2015 – 06.05.2015</b>  |   |   |  |
| <b>Ort der Prüfung:</b><br><i>Place of testing:</i>   | <b>Prüfstelle für Textilien und PSA Leipzig</b>   |   |   |  |
| <b>Prüflaboratorium:</b><br><i>Testing laboratory:</i>  | <b>TÜV Rheinland LGA Products GmbH</b>  |   |   |  |
| <b>Prüfergebnis*:</b><br><i>Test result*:</i>   | <b>Pass</b>   |   |   |  |
| <b>geprüft von / tested by:</b>   |   | <b>kontrolliert von / reviewed by:</b>  |   |  |
| <b>07.05.2015</b>   | <b>J. Voigt / Sachverständiger/Expert</b>   | <b>07.05.2015</b>   | <b>M. Schultz / Sachverständiger/Expert</b> |  |
| <b>Datum</b><br><i>Date</i>   | <b>Name / Stellung</b><br><i>Name / Position</i>  | <b>Unterschrift</b><br><i>Signature</i>   | <b>Datum</b><br><i>Date</i>                 | <b>Name / Stellung</b><br><i>Name / Position</i> |
|   |   |   |   | <b>Unterschrift</b><br><i>Signature</i>          |
| <b>Sonstiges / Other:</b>   |   |   |   |  |
| <b>Zustand des Prüfgegenstandes bei Anlieferung:</b><br><i>Condition of the test item at delivery:</i>  |   | <b>Prüfmuster vollständig und unbeschädigt</b><br><i>Test item complete and undamaged</i> |   |  |
| <p>* Legende: 1 = sehr gut 2 = gut 3 = befriedigend 4 = ausreichend 5 = mangelhaft<br/> P(ass) = entspricht o.g. Prüfgrundlage(n) F(ail) = entspricht nicht o.g. Prüfgrundlage(n) N/A = nicht anwendbar N/T = nicht getestet</p> <p>Legend: 1 = very good 2 = good 3 = satisfactory 4 = sufficient 5 = poor<br/> P(ass) = passed a.m. test specification(s) F(ail) = failed a.m. test specification(s) N/A = not applicable N/T = not tested</p>                    |   |   |   |  |
| <p><b>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.</b><br/> <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></p> |   |   |   |  |

v04



**Prüfbericht-Nr.: 21231212\_001**  
*Test Report No.:*

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**Liste der verwendeten Prüfmittel**  
*List of used test equipment*

[illegible]



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Test Report No.:

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**Produktbeschreibung**  
**Product description**

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

Nitrile glove, 12 inches, blue, powder free





|               |   |                                    |                   |
|---------------|---|------------------------------------|-------------------|
| Absatz        | <b>EN 374-1:2003, EN 374-2:2003, EN 374-3:2003</b>      | Messergebnisse - Bemerkungen       | Bewertung         |
| <i>Clause</i> | <i>Anforderungen - Prüfungen / Requirements - Tests</i> | <i>Measuring results - Remarks</i> | <i>Evaluation</i> |

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



Prüfbericht-Nr.: 21231212\_001  
Test Report No.:

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| Absatz          | EN 374-1:2003, EN 374-2:2003, EN 374-3:2003   |                   | Messergebnisse - Bemerkungen    | Bewertung   |
|-----------------|---|-------------------|---------------------------------|---|
| Clause          | Anforderungen - Prüfungen / Requirements - Tests  |                   | Measuring results - Remarks     | Evaluation  |
|                 | Azo-Farbstoffe<br>Azo dye stuff   |                   |                                 |   |
|                 | < 30 mg/kg<br><br>nach / according to: 1907/2006/EU   | ---               |                                 | P <input type="checkbox"/><br>F <input type="checkbox"/><br>N/A <input checked="" type="checkbox"/><br>N/T <input type="checkbox"/> |
| EN 420<br>4.3.2 | Bestimmung des pH-Wertes<br>Determination of pH-value   |                   |                                 |   |
|                 | Der pH-Wert für Handschuhe muss größer als 3,5 und kleiner als 9,5 sein.<br><br>The pH value for all gloves shall be greater than 3,5 and less than 9,5.  | Innenhand<br>Palm | pH-Wert<br>pH- value<br><br>6,8 | P <input checked="" type="checkbox"/><br>F <input type="checkbox"/><br>N/A <input type="checkbox"/><br>N/T <input type="checkbox"/> |
| EN 420<br>4.3.3 | Bestimmung des Chrom(VI)-Gehaltes<br>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.<br><br>The quantity of Chromium VI in gloves containing leather shall not exceed 3,0 mg/kg when determined according to the test method described in EN ISO 17075:2007. If the glove includes different types of leather, whether in contact with the skin or not, each leather type shall be tested separately and comply with the above requirement. | ---               |                                 | P <input type="checkbox"/><br>F <input type="checkbox"/><br>N/A <input checked="" type="checkbox"/><br>N/T <input type="checkbox"/> |
| EN 420<br>4.3.4 | Bestimmung des Protein Gehaltes<br>Determination of extractable protein content   |                   |                                 |   |
|                 | Schutzhandschuhe aus Naturkautschuk müssen hinsichtlich ihres extrahierbaren Proteingehalts die in EN 455-3 festgelegten Anforderungen erfüllen.<br>Naturkautschuk: Lowry- Prüfmethode<br>so gering wie vernünftigerweise praktikabel (ALARP)<br><br>Natural rubber gloves shall be submitted to requirements stated in EN 455-3 on extractable protein content.<br>natural rubber: latex Lowry- test method<br>as low as reasonably practicable (ALARP)  | ---               |                                 | P <input type="checkbox"/><br>F <input type="checkbox"/><br>N/A <input checked="" type="checkbox"/><br>N/T <input type="checkbox"/> |



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| Absatz                       | EN 374-1:2003, EN 374-2:2003, EN 374-3:2003  |                                  |  |                                  | Messergebnisse - Bemerkungen                                   | Bewertung   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
|------------------------------|--|----------------------------------|--|----------------------------------|--|---|-----|-----|-----|---|-----|-----|-----|---|-----|-----|-----|---|-----|-----|-----|----|-----|-----|-----|----|-----|-----|-----|--|---------------|--|---|-----|---|-----|---|-----|---|-----|----|-----|----|-----|---|
| Clause                       | Anforderungen - Prüfungen / Requirements - Tests   |                                  |  |                                  | Measuring results - Remarks                                    | Evaluation  |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| EN 420 4.4                   | Reinigung<br>Cleaning  |                                  |  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
|                              | Sofern Pflegeanweisungen angegeben sind, sind die in den spezifischen Normen aufgeführten relevanten Prüfungen an den Handschuhen durchzuführen, bevor und nachdem sie der höchsten empfohlenen Anzahl von Reinigungen unterzogen worden sind. Die Leistungsstufen dürfen durch die empfohlene Anzahl der Reinigungen nicht negativ beeinflusst werden.<br><br>If care instructions are provided, the relevant tests of the specific standards shall be performed on the gloves, before and after they have been subjected to the maximum recommended number of cleaning cycles. The levels of performance shall not be negatively affected throughout the recommended number of cycles. |                                  |  |                                  | ---  | P <input type="checkbox"/><br>F <input type="checkbox"/><br>N/A <input checked="" type="checkbox"/><br>N/T <input type="checkbox"/> |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| EN 420 4.5                   | Elektrostatische Eigenschaften<br>Electrostatic properties   |                                  |  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
|                              | wenn erforderlich/ if required:<br>Das Prüfergebn muss in den Herstellerinformationen angegeben werden zusammen mit den Informationen nach 7.3.11. Es dürfen keine Piktogramme für elektrostatische Eigenschaften verwendet werden.<br><br>The test result shall be reported in the information supplied by the manufacturer accompanied by the information stated in 7.3.11. Electrostatic pictograms shall not be used for this property.  |                                  |  |                                  | ---  | P <input type="checkbox"/><br>F <input type="checkbox"/><br>N/A <input checked="" type="checkbox"/><br>N/T <input type="checkbox"/> |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| EN 420 5                     | Komfort und Leistungsfähigkeit<br>Comfort and efficiency   |                                  |  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| EN 420 5.1                   | Größen<br>Sizing   |                                  |  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| EN 420 5.1.2                 | Größen und Maße der Handschuhe<br>Sizes and measurements of glove  |                                  |  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| Tab. 2, Tab. 3               | <table><tr><th>Handschuhgröße<br/>Glove size</th><th>Handumfang<br/>Hand circumference<br/>[mm]</th><th>Handlänge<br/>Hand length<br/>[mm]</th><th>Mindestlänge des Handschuhs<br/>Minimum length of glove<br/>[mm]</th></tr><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></table>  | Handschuhgröße<br>Glove size     | Handumfang<br>Hand circumference<br>[mm]                       | Handlänge<br>Hand length<br>[mm] | Mindestlänge des Handschuhs<br>Minimum length of glove<br>[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><tr><th>Größe<br/>Size</th><th>Handschuhlänge<br/>Glove length<br/>[mm]</th></tr><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></table> | Größe<br>Size | Handschuhlänge<br>Glove length<br>[mm] | 6 | 298 | 7 | 300 | 8 | 301 | 9 | 299 | 10 | 305 | 11 | --- | P <input checked="" type="checkbox"/><br>F <input type="checkbox"/><br>N/A <input type="checkbox"/><br>N/T <input type="checkbox"/> |
| Handschuhgröße<br>Glove size | Handumfang<br>Hand circumference<br>[mm]   | Handlänge<br>Hand length<br>[mm] | Mindestlänge des Handschuhs<br>Minimum length of glove<br>[mm] |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| 6                            | 152  | 160                              | 220  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| 7                            | 178  | 171                              | 230  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| 8                            | 203  | 182                              | 240  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| 9                            | 229  | 192                              | 250  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| 10                           | 254  | 204                              | 260  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| 11                           | 279  | 215                              | 270  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| Größe<br>Size                | Handschuhlänge<br>Glove length<br>[mm]   |                                  |  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| 6                            | 298  |                                  |  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| 7                            | 300  |                                  |  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| 8                            | 301  |                                  |  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| 9                            | 299  |                                  |  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| 10                           | 305  |                                  |  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |
| 11                           | ---  |                                  |  |                                  |  |   |     |     |     |   |     |     |     |   |     |     |     |   |     |     |     |    |     |     |     |    |     |     |     |  |               |  |   |     |   |     |   |     |   |     |    |     |    |     |   |



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



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| Absatz                             | EN 374-1:2003, EN 374-2:2003, EN 374-3:2003  |                                | Messergebnisse - Bemerkungen       | Bewertung   |                                |                  |        |    |                  |       |    |                  |       |    |   |  |  |                    |                  |  |    |   |  |                    |                  |  |    |   |
|------------------------------------|--|--------------------------------|------------------------------------|---|--------------------------------|------------------|--------|----|------------------|-------|----|------------------|-------|----|---|--|--|--------------------|------------------|--|----|---|--|--------------------|------------------|--|----|---|
| Clause                             | Anforderungen - Prüfungen / Requirements - Tests   |                                | Measuring results - Remarks        | Evaluation  |                                |                  |        |    |                  |       |    |                  |       |    |   |  |  |                    |                  |  |    |   |  |                    |                  |  |    |   |
| 4                                  | Prüfverfahren<br>Method of testing   |                                |                                    |   |                                |                  |        |    |                  |       |    |                  |       |    |   |  |  |                    |                  |  |    |   |  |                    |                  |  |    |   |
|                                    | Ausführliche Prüfverfahren werden in folgenden Teilen dieser Norm angegeben / detailed test methods will be found in the following parts of this standard:<br><br>Penetration      EN 374-2 / Penetration      EN 374-2<br>Permeation      EN 374-3 / Permeation      EN 374-3   |                                |                                    |   |                                |                  |        |    |                  |       |    |                  |       |    |   |  |  |                    |                  |  |    |   |  |                    |                  |  |    |   |
| 5                                  | Anforderungen<br>Performance requirements  |                                |                                    |   |                                |                  |        |    |                  |       |    |                  |       |    |   |  |  |                    |                  |  |    |   |  |                    |                  |  |    |   |
| 5.1                                | Kleinste flüssigkeitsundurchdringliche Länge<br>Minimum liquid proof length  |                                |                                    | P <input type="checkbox"/><br>F <input type="checkbox"/><br>N/A <input checked="" type="checkbox"/><br>N/T <input type="checkbox"/> |                                |                  |        |    |                  |       |    |                  |       |    |   |  |  |                    |                  |  |    |   |  |                    |                  |  |    |   |
| 5.2                                | Penetration<br>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.<br><br>Gloves shall not leak when tested according to the test methods in EN 374-2 (5.2 and 5.3) and both test shall be passed according to the criteria in the relevant clauses of EN 374-2. If one test proves unsuitable, the reason shall be reported. |                                |                                    |   |                                |                  |        |    |                  |       |    |                  |       |    |   |  |  |                    |                  |  |    |   |  |                    |                  |  |    |   |
| 5.2.2                              | Ein Handschuh wird als beständig gegen Mikroorganismen angesehen, wenn er mindestens der Stufe 2 bei der Prüfung gegen Penetration nach Anhang A der EN 374-2 entspricht.<br><br>A glove shall be considered as micro-organism resistant when it conforms to at least level 2 of the penetration test of annex A of EN 374-2.  |                                |                                    |   |                                |                  |        |    |                  |       |    |                  |       |    |   |  |  |                    |                  |  |    |   |  |                    |                  |  |    |   |
| Tab. A1                            | <table><tr><th>Leistungsstufe / performance level</th><th>Annehmbare Qualitätsrenzlage / acceptable quality level unit</th><th>Prüfniveau / Inspection levels</th></tr><tr><td>Niveau / level 3</td><td>&lt; 0,65</td><td>G1</td></tr><tr><td>Niveau / level 2</td><td>&lt; 1,5</td><td>G1</td></tr><tr><td>Niveau / level 1</td><td>&lt; 4,0</td><td>S4</td></tr></table><br><div>Luft-Leck-Prüfung / Air leakage</div> <div>Wasser-Leck-Prüfung / Water leakage</div>  |                                | 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 | <div>geprüfte Menge/<br/>tested quantity:<br/>10 Stück/pieces</div> <div>akzeptierte Fehler/<br/>accepted defects:<br/>0 Stück/pieces</div> <div>Luft-Leck-Prüfung / Air leakage</div> <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> <div>Wasser-Leck-Prüfung / Water leakage</div> <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> <div>P      <input checked="" type="checkbox"/><br/>F      <input type="checkbox"/><br/>N/A      <input type="checkbox"/><br/>N/T      <input type="checkbox"/></div> |  |  | dicht/ not leaking | undicht/ leaking |  | 10 | 0 |  | dicht/ not leaking | undicht/ leaking |  | 10 | 0 |
| 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                             |                                    |   |                                |                  |        |    |                  |       |    |                  |       |    |   |  |  |                    |                  |  |    |   |  |                    |                  |  |    |   |
|                                    | dicht/ not leaking   | undicht/ leaking               |                                    |   |                                |                  |        |    |                  |       |    |                  |       |    |   |  |  |                    |                  |  |    |   |  |                    |                  |  |    |   |
|                                    | 10   | 0                              |                                    |   |                                |                  |        |    |                  |       |    |                  |       |    |   |  |  |                    |                  |  |    |   |  |                    |                  |  |    |   |
|                                    | dicht/ not leaking   | undicht/ leaking               |                                    |   |                                |                  |        |    |                  |       |    |                  |       |    |   |  |  |                    |                  |  |    |   |  |                    |                  |  |    |   |
|                                    | 10   | 0                              |                                    |   |                                |                  |        |    |                  |       |    |                  |       |    |   |  |  |                    |                  |  |    |   |  |                    |                  |  |    |   |



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| Clause | Anforderungen - Prüfungen / Requirements - Tests | Measuring results - Remarks  | Evaluation |

|   |  |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
|---|--|--|--|--|------|------------------------------|-----------------------------|-------------------------|----------------------------|-------------------------|-------------------------|-------------------------|-----------------------------------|-------------------------|---|-------------------------|--|---|--|--|-----------------------------------|---|---|------|------------------------------------|----|--|---|---|---|---|
| 5.3   | <b>Permeation</b><br><b>Permeation</b>   |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| 5.3.1   | <p>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</p> <p><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></p>  |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| 5.3.2   | <p>Ein Handschuh wird als beständig gegen Chemikalien angesehen, wenn ein Schutzindex von mindestens Klasse 2 bei drei Prüfchemikalien nach Anhang A erhalten wird.</p> <p><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></p> <div><div>Anhang A/<br/>Annex A</div><table><tr><td>Kennbuchstabe<br/>Code letter</td><td>Prüfchemikalien<br/>Chemical</td></tr><tr><td>A</td><td>Methanol / <i>Methanol</i></td></tr><tr><td>B</td><td>Aceton / <i>Acetone</i></td></tr><tr><td>C</td><td>Acetonitril / <i>Acetonitrile</i></td></tr><tr><td>D</td><td>Dichloromethan / <i>Dichloromethane</i></td></tr><tr><td>E</td><td>Kohlenstoffdisulfid / <i>Carbon disulphide</i></td></tr><tr><td>F</td><td>Toluol / <i>Toluene</i></td></tr><tr><td>G</td><td>Diethylamin / <i>Diethylamine</i></td></tr><tr><td>H</td><td>Tetrahydrofuran / <i>Tetrahydrofurane</i></td></tr><tr><td>I</td><td>Ethylacetat / <i>Ethyl acetate</i></td></tr><tr><td>J</td><td>n-Heptan / <i>n-Heptane</i></td></tr><tr><td>K</td><td>Natriumhydroxid 40 % / <i>Sodium hydroxide 40 %</i></td></tr><tr><td>L</td><td>Schwefelsäure 96 % / <i>Sulphuric acid 96 %</i></td></tr></table></div> |  |  |  |      | Kennbuchstabe<br>Code letter | Prüfchemikalien<br>Chemical | 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<br>Code letter  | Prüfchemikalien<br>Chemical  |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| 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>  |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| Tab. 1  | <table><tr><td>Durchbruchzeit /<br/><i>Measured breakthrough time</i><br/>[min]</td><td>Schutzindex /<br/><i>Permeation performance level</i></td></tr><tr><td>&gt; 10</td><td>Klasse / <i>class 1</i></td></tr><tr><td>&gt; 30</td><td>Klasse / <i>class 2</i></td></tr><tr><td>&gt; 60</td><td>Klasse / <i>class 3</i></td></tr><tr><td>&gt; 120</td><td>Klasse / <i>class 4</i></td></tr><tr><td>&gt; 240</td><td>Klasse / <i>class 5</i></td></tr><tr><td>&gt; 480</td><td>Klasse / <i>class 6</i></td></tr></table>   |  | Durchbruchzeit /<br><i>Measured breakthrough time</i><br>[min] | Schutzindex /<br><i>Permeation performance level</i> | > 10 | Klasse / <i>class 1</i>      | > 30                        | Klasse / <i>class 2</i> | > 60                       | Klasse / <i>class 3</i> | > 120                   | Klasse / <i>class 4</i> | > 240                             | Klasse / <i>class 5</i> | > 480                                   | Klasse / <i>class 6</i> | /* <table><tr><td>Prüf-<br/>chemikalie /<br/><i>Chemical</i></td><td>Durchbruchzeit /<br/><i>Measured breakthrough time</i><br/>[min]</td></tr><tr><td>Ethyl acetate</td><td>0</td></tr><tr><td>NaOH 40%</td><td>&gt;480</td></tr><tr><td>H<sub>2</sub>SO<sub>4</sub> 96%</td><td>22</td></tr></table> |   | Prüf-<br>chemikalie /<br><i>Chemical</i> | Durchbruchzeit /<br><i>Measured breakthrough time</i><br>[min] | Ethyl acetate                     | 0 | NaOH 40%                                  | >480 | H <sub>2</sub> SO <sub>4</sub> 96% | 22 | <div><div>P<input checked="" type="checkbox"/></div><div>F<input type="checkbox"/></div><div>N/A<input type="checkbox"/></div><div>N/T<input type="checkbox"/></div><div>Level 0</div><div>Level 6</div><div>Level 1</div></div> |   |   |   |   |
| Durchbruchzeit /<br><i>Measured breakthrough time</i><br>[min]                          | Schutzindex /<br><i>Permeation performance level</i>   |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| > 10  | Klasse / <i>class 1</i>  |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| > 30  | Klasse / <i>class 2</i>  |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| > 60  | Klasse / <i>class 3</i>  |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| > 120   | Klasse / <i>class 4</i>  |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| > 240   | Klasse / <i>class 5</i>  |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| > 480   | Klasse / <i>class 6</i>  |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| Prüf-<br>chemikalie /<br><i>Chemical</i>  | Durchbruchzeit /<br><i>Measured breakthrough time</i><br>[min]   |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| Ethyl acetate   | 0  |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| NaOH 40%  | >480   |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| H <sub>2</sub> SO <sub>4</sub> 96%  | 22   |  |  |  |      |                              |                             |                         |                            |                         |                         |                         |                                   |                         |   |                         |  |   |  |  |                                   |   |   |      |                                    |    |  |   |   |   |   |
| Schutz gegen geringe chemische Risiken/<br><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 | Leistungsstufe<br>Performance level                          | Abriebfestigkeit [Zyklen]<br>Abrasion [cycles] | Durchbruch bei ca. [Zyklen]<br>Breakthrough at about [cycles]                        | P <input checked="" type="checkbox"/> |
|        | 1  | 100  | 1. Lage / layer   2. Lage / layer  | F <input type="checkbox"/>            |
|        | 2  | 500  | 100-500   ---  | N/A <input type="checkbox"/>          |
|        | 3  | 2000   | 500-2000   ---   | N/T <input type="checkbox"/>          |
|        | 4  | 8000   | 500-2000   ---   |                                       |
|        | Schleifpapier / abrasive paper:<br>Klingspor PL31B Gritt 180 |  | niedrigster Wert zur<br>Klassifizierung / lowest value<br>for classification:<br>100 | Stufe /<br>level 1                    |

#### EN 388 6.2 Schnittfestigkeit Blade cut resistance

|        |                                     |   |   |   |
|--------|-------------------------------------|---|---|---|
| Tab. 1 | Leistungsstufe<br>Performance level | Schnittfestigkeit [Faktor]<br>Blade cut resistance [Factor] | Index i: 1,1 1,1  | P <input type="checkbox"/>              |
|        | 1                                   | 1,2   | 1,1 1,1   | F <input type="checkbox"/>              |
|        | 2                                   | 2,5   | 1,1 1,1   | N/A <input checked="" type="checkbox"/> |
|        | 3                                   | 5,0   | 1,1 1,1   | N/T <input type="checkbox"/>            |
|        | 4                                   | 10,0  | 1,1 1,1   |   |
|        | 5                                   | 20,0  | Index I: 1,1 1,1  |   |
|        |                                     |   | niedrigster Index I zur<br>Klassifizierung / lowest Index I<br>for classification:<br>1,1 | Stufe /<br>level 0                      |



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

| EN 388<br>6.3                                | Weiterreißfestigkeit<br><i>Tear resistance</i>   |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
|--|--|--|--|---|----|---|----|---|-----|---|-----|--|--|--|------------------------|------------------------|-------|-------|---|---|------|-----|------|-----|---|--|
| Tab. 1                                       | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="padding: 2px;">Leistungsstufe<br/><i>Performance level</i></th> <th style="padding: 2px;">Weiterreißfestigkeit [N]<br/><i>Tear resistance [N]</i></th> </tr> <tr><td style="text-align: center;">1</td><td style="text-align: center;">10</td></tr> <tr><td style="text-align: center;">2</td><td style="text-align: center;">25</td></tr> <tr><td style="text-align: center;">3</td><td style="text-align: center;">50</td></tr> <tr><td style="text-align: center;">4</td><td style="text-align: center;">75</td></tr> </table>       | Leistungsstufe<br><i>Performance level</i> | Weiterreißfestigkeit [N]<br><i>Tear resistance [N]</i>     | 1 | 10 | 2 | 25 | 3 | 50  | 4 | 75  | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="padding: 2px;">Einzelwerte [N]<br/><i>Several values [N]</i></th> </tr> <tr> <th style="padding: 2px;">1. Lage / <i>layer</i></th> <th style="padding: 2px;">2. Lage / <i>layer</i></th> </tr> <tr><td style="text-align: center;">1,78</td><td style="text-align: center;">---</td></tr> <tr><td style="text-align: center;">1,97</td><td style="text-align: center;">---</td></tr> <tr><td style="text-align: center;">1,92</td><td style="text-align: center;">---</td></tr> <tr><td style="text-align: center;">1,67</td><td style="text-align: center;">---</td></tr> </table> | Einzelwerte [N]<br><i>Several values [N]</i> |  | 1. Lage / <i>layer</i> | 2. Lage / <i>layer</i> | 1,78  | ---   | 1,97  | ---   | 1,92 | --- | 1,67 | --- | P <input type="checkbox"/><br>F <input type="checkbox"/><br>N/A <input checked="" type="checkbox"/><br>N/T <input type="checkbox"/> | niedrigster Wert zur<br>Klassifizierung / <i>lowest value</i><br>for classification:<br><div style="text-align: right;">1,67 N</div> |
| Leistungsstufe<br><i>Performance level</i>   | Weiterreißfestigkeit [N]<br><i>Tear resistance [N]</i>   |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 1  | 10   |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 2  | 25   |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 3  | 50   |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 4  | 75   |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| Einzelwerte [N]<br><i>Several values [N]</i> |  |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 1. Lage / <i>layer</i>                       | 2. Lage / <i>layer</i>   |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 1,78   | ---  |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 1,97   | ---  |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 1,92   | ---  |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 1,67   | ---  |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| EN 388<br>6.4                                | Durchstichfestigkeit<br><i>Puncture resistance</i>   |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| Tab. 1                                       | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="padding: 2px;">Leistungsstufe<br/><i>Performance level</i></th> <th style="padding: 2px;">Durchstichfestigkeit [N]<br/><i>Puncture resistance [N]</i></th> </tr> <tr><td style="text-align: center;">1</td><td style="text-align: center;">20</td></tr> <tr><td style="text-align: center;">2</td><td style="text-align: center;">60</td></tr> <tr><td style="text-align: center;">3</td><td style="text-align: center;">100</td></tr> <tr><td style="text-align: center;">4</td><td style="text-align: center;">150</td></tr> </table> | Leistungsstufe<br><i>Performance level</i> | Durchstichfestigkeit [N]<br><i>Puncture resistance [N]</i> | 1 | 20 | 2 | 60 | 3 | 100 | 4 | 150 | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="padding: 2px;">Einzelwerte [N]<br/><i>several values [N]</i></th> </tr> <tr> <td style="padding: 2px;">21,22</td> <td style="padding: 2px;">27,88</td> </tr> <tr> <td style="padding: 2px;">26,88</td> <td style="padding: 2px;">26,20</td> </tr> </table>  | Einzelwerte [N]<br><i>several values [N]</i> |  | 21,22                  | 27,88                  | 26,88 | 26,20 | P <input checked="" type="checkbox"/><br>F <input type="checkbox"/><br>N/A <input type="checkbox"/><br>N/T <input type="checkbox"/> | niedrigster Wert zur<br>Klassifizierung / <i>lowest value</i><br>for classification:<br><div style="text-align: right;">21,22 N</div> |      |     |      |     |   |  |
| Leistungsstufe<br><i>Performance level</i>   | Durchstichfestigkeit [N]<br><i>Puncture resistance [N]</i>   |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 1  | 20   |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 2  | 60   |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 3  | 100  |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 4  | 150  |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| Einzelwerte [N]<br><i>several values [N]</i> |  |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 21,22  | 27,88  |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |
| 26,88  | 26,20  |  |  |   |    |   |    |   |     |   |     |  |  |  |                        |                        |       |       |   |   |      |     |      |     |   |  |




|          |   |  |  |  |
|----------|---|--|--|--|
| <b>6</b> | <b>Kennzeichnung<br/>Marking</b>  |  |  |  |
|          | 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.<br><br><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<br>7.1 | Kennzeichnung und Information – Allgemeines<br><i>Marking and Information – General</i>  |                              |   |  |
|               | Alle Angaben müssen präzise und umfassend sein und mindestens in der offiziellen Sprache des Bestimmungslandes.<br><br><i>All details have to be precise and in official language of country of destination.</i> | gegeben<br><br><br><br>given | P <input checked="" type="checkbox"/><br>F <input type="checkbox"/><br>N/A <input type="checkbox"/><br>N/T <input type="checkbox"/> |  |



**Prüfbericht-Nr.: 21231212\_001**  
**Test Report No.:**

| Absatz<br>Clause | EN 374-1:2003, EN 374-2:2003, EN 374-3:2003<br>Anforderungen - Prüfungen / Requirements - Tests  | Messergebnisse - Bemerkungen<br>Measuring results - Remarks   | Bewertung<br>Evaluation  |
|------------------|--|---|--|
| EN 420<br>7.2    | Kennzeichnung und Information – Kennzeichnung<br><i>Marking and Information – Marking</i>  |   |  |
| EN 420<br>7.2.1  | <p>Jeder Schutzhandschuh muss mit folgenden Angaben gekennzeichnet sein:</p> <ul style="list-style-type: none"> <li>- Name, Handelsmarke oder andere Erkennungsmerkmale des Herstellers oder seines Repräsentanten</li> <li>- Handschuhbezeichnung (Handelsname oder Code, der dem Anwender die eindeutige Identifizierung des Produkts innerhalb des Sortiments des Herstellers oder bevollmächtigten Repräsentanten erlaubt)</li> <li>- Größenbezeichnung</li> <li>- Kennzeichnung mit Verfallsdatum</li> <li>- das Piktogramm mit der Nummer der Norm und die Leistungsstufen</li> </ul> <p><i>Each protective glove shall be marked with the following information:</i></p> <ul style="list-style-type: none"> <li>- Name, trade mark or other means of identification of manufacturer or his authorized representative</li> <li>- Glove designation (commercial name or code allowing the user to identify clearly the product within the manufacturer's/authorized representative's range)</li> <li>- Size designation</li> <li>- Marking with date of obsolescence</li> <li>- Pictogram with number of standard and performance levels</li> </ul> | <p>Diese Information befindet sich auf Verpackung<br/>Hebei Hongsen Plastics Technology Co., Ltd.<br/>Titanfine REF HS6213, HS6214, HS6215, HS6216, HS6217</p> <p>z.B. M<br/>Platzhalter gegeben<br/>gegeben</p> <p><i>This information is available on the packing<br/>Hebei Hongsen Plastics Technology Co., Ltd.<br/>Titanfine REF HS6213, HS6214, HS6215, HS6216, HS6217<br/>e.g. M<br/>placeholder given<br/>given</i></p> | <p>P <input checked="" type="checkbox"/></p> <p>F <input type="checkbox"/></p> <p>N/A <input type="checkbox"/></p> <p>N/T <input type="checkbox"/></p> |
|                  | <p>für Schutzhandschuhe, die die Anforderungen an Penetration und Permeation erfüllen – Piktogramm für chemische Gefahren</p> <p><i>for gloves complying to the requirements for penetration and permeation – chemical pictogram:</i></p>   | ---   | <p>P <input type="checkbox"/></p> <p>F <input type="checkbox"/></p> <p>N/A <input checked="" type="checkbox"/></p> <p>N/T <input type="checkbox"/></p> |
|                  | <p>oder/or</p> <p>für Schutzhandschuhe, die nur die Anforderungen an die Penetration erfüllen – Piktogramm für wasserfeste Schutzhandschuhe und geringen Schutz gegen chemische Gefahren / <i>for gloves complying tot he requirement for penetration – pictrogram for waterproof gloves with low chemical protection</i></p>    | <p>gegeben</p> <p><i>given</i></p>  | <p>P <input checked="" type="checkbox"/></p> <p>F <input type="checkbox"/></p> <p>N/A <input type="checkbox"/></p> <p>N/T <input type="checkbox"/></p> |



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| Absatz          | EN 374-1:2003, EN 374-2:2003, EN 374-3:2003   | Messergebnisse - Bemerkungen   | Bewertung  |
|-----------------|---|--|--|
| Clause          | Anforderungen - Prüfungen / Requirements - Tests  | Measuring results - Remarks  | Evaluation   |
| EN 420<br>7.2.2 | Kennzeichnung und Information – Kennzeichnung der Verpackung<br><i>Marking and Information – Marking of Packaging</i>   |  |  |
|                 | <p>Jede kleinste Verpackungseinheit, welche den Handschuh unmittelbar enthält, muss eindeutig mit den nachfolgenden Angaben gekennzeichnet sein:</p> <ul style="list-style-type: none"> <li>- Name und volle Anschrift des Herstellers oder seines autorisierten Repräsentanten</li> <li>- Handschuhbezeichnung (Handelsname oder Code, der dem Anwender die eindeutige Identifizierung des Produkts innerhalb des Sortiments des Herstellers oder bevollmächtigten Repräsentanten erlaubt)</li> <li>- Größenbezeichnung</li> <li>- Kennzeichnung mit Verfallsdatum</li> <li>- Hinweis, wo die Information des Herstellers zu erhalten ist</li> <li>- bei einfachen Handschuhen der Hinweis, „Nur bei minimalen Gefahren“ o. ä.</li> <li>- das Piktogramm mit der Nummer der Norm und die Leistungsstufen</li> <li>- CE-Zeichen gemäß Richtlinie 89/686/EWG</li> </ul> <p><i>Each packaging enclosure that immediately contains the gloves shall be clearly marked with the following:</i></p> <ul style="list-style-type: none"> <li>- <i>Name, trade mark or other means of identification of manufacturer or his authorized representative</i></li> <li>- <i>Glove designation (commercial name or code allowing the user to identify clearly the product within the manufacturer's/authorized representative's range)</i></li> <li>- <i>Size designation</i></li> <li>- <i>Marking with date of obsolescence</i></li> <li>- <i>Note where the information of the manufacturer is to obtain</i></li> <li>- <i>for simple gloves note "Only for minimal risks" etc.</i></li> <li>- <i>Pictogram with number of standard and performance levels</i></li> <li>- <i>CE-mark in accordance to Directive 89/686/EEC</i></li> </ul> | <p>Hebei Hongsen Plastics Technology Co., Ltd.<br/>Titanfine REF HS6213, HS6214, HS6215, HS6216, HS6217</p> <p>z.B. M<br/>Platzhalter gegeben<br/>gegeben</p> <p>N/A<br/>gegeben<br/>gegeben</p> <p>Hebei Hongsen Plastics Technology Co., Ltd.<br/>Titanfine REF HS6213, HS6214, HS6215, HS6216, HS6217<br/>e.g. M<br/>placeholder given<br/>gegeben</p> <p>N/A<br/>given<br/>given</p> | <p>P <input checked="" type="checkbox"/></p> <p>F <input type="checkbox"/></p> <p>N/A <input type="checkbox"/></p> <p>N/T <input type="checkbox"/></p> |



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

|               |  |  |  |
|---------------|--|--|--|
| 7             | <b>Information des Herstellers</b><br><b>Information supplied by the manufacturer</b>  |  |  |
|               | <p>Informationen des Herstellers müssen den Anforderungen in EN 420 entsprechen.</p> <p><i>The information supplied by the manufacturer shall be in accordance with the requirements for information as defined in EN 420.</i></p>   |  |  |
| EN 420<br>7.3 | <p>Folgende Mindestinformationen müssen beigefügt werden:</p> <ul style="list-style-type: none"> <li>- Name und volle Anschrift des Herstellers oder seines autorisierten Repräsentanten</li> <li>- Artikelbezeichnung, Code oder Nr.</li> <li>- Informationen über verfügbare Größen</li> <li>- EN 374: 2003 und/ oder EN 388:2003, mit Piktogramm und Leistungsstufen</li> <li>- falls erforderlich, Verfallsdatum</li> <li>- Informationen, wenn der Schutz nur für Teile der PSA gewährleistet ist</li> <li>- mögliche Probleme</li> <li>- Gebrauchsanweisung, auch beim Gebrauch mit anderen PSA</li> <li>- Pflegekennzeichnung</li> </ul> <p><i>The following minimum information shall be supplied:</i></p> <ul style="list-style-type: none"> <li>- Name and full address of manufacturer or his authorized representative</li> <li>- Glove designation</li> <li>- Information on available size range</li> <li>- Reference to EN 374:2003 or/ and EN 388:2003 pictogram with performance levels</li> <li>- if the expected shelf-life of the gloves is reduced by aging, the expiration date have to be added</li> <li>- if protection is only given, for part of gloves, information have to be added</li> <li>- possible problems</li> <li>- instruction for use for gloves and also for use with combination of other PPE</li> <li>- care label</li> </ul> | <p>Hebei Hongsen Plastics Technology Co., Ltd.<br/>Titanfine REF HS6213, HS6214, HS6215, HS6216, HS6217</p> <p>gegeben<br/>gegeben</p> <p>gegeben<br/>N/A</p> <p>gegeben<br/>N/A</p> <p>N/A</p> <p>Hebei Hongsen Plastics Technology Co., Ltd.<br/>Titanfine REF HS6213, HS6214, HS6215, HS6216, HS6217</p> <p>given<br/>given</p> <p>given</p> <p>N/A</p> <p>given<br/>N/A</p> <p>N/A</p> | <p>P <input checked="" type="checkbox"/></p> <p>F <input type="checkbox"/></p> <p>N/A <input type="checkbox"/></p> <p>N/T <input type="checkbox"/></p> |



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| Absatz | EN 374-1:2003, EN 374-2:2003, EN 374-3:2003   | Messergebnisse - Bemerkungen  | Bewertung  |
|--------|---|---|--|
| Clause | Anforderungen - Prüfungen / Requirements - Tests  | Measuring results - Remarks   | Evaluation   |
|        | <p>Zusatzinformationen:</p> <ul style="list-style-type: none"> <li>- Einzelheiten zu besonderen Prüfungen, die unter anderen klimatischen Bedingungen durchgeführt wurden, müssen angegeben werden</li> <li>- 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</li> <li>- Ein Warnhinweis muss enthalten sein, dass in Fällen, bei denen ein Risiko besteht, sich in bewegten Maschinenteilen zu verfangen, keine Handschuhe getragen werden sollten</li> <li>- 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.</li> <li>- 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.</li> <li>- Die Leistungsstufe und die annehmbare Qualitätsgrenzlage (AQL) für die Prüfung der Penetration in der Produktion sind anzugeben.</li> </ul> <p>Additional information:</p> <ul style="list-style-type: none"> <li>- details of any special tests carried out in a different environment shall be given</li> <li>- 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</li> <li>- users should be warned that gloves should not be worn when there is a risk of entanglement by moving parts of machines</li> <li>- 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.</li> <li>- 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.</li> <li>- The level of performance and associated AQL for penetration production control shall be reported.</li> </ul> | <p>N/A</p> <p>N/A</p> <p>gegeben</p> <p>gegeben</p> <p>gegeben</p> <p>N/A</p> <p>N/A</p> <p>N/A</p> <p>given</p> <p>given</p> <p>given</p> <p>N/A</p> | <p>P <input checked="" type="checkbox"/></p> <p>F <input type="checkbox"/></p> <p>N/A <input type="checkbox"/></p> <p>N/T <input type="checkbox"/></p> |



Certificate of Registration



This is to certify that the Quality Management System of

**Super Safe Plastic Products Co., Ltd.**

Meng Er Village, Pingshan County, Shijiazhuang, Hebei Province, China

applicable to

**Production and sales of disposable PVC surgical examination gloves and ordinary PVC gloves**

has been assessed and registered by NQA against the provisions of  
**ISO 9001:2008**

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.  
Please consult the website: [www.snqa.com.cn](http://www.snqa.com.cn)

*Alan West*

Certification Director



013

Certificate Number **29112**

Date: 13 September 2013

Valid Until: 13 September 2016

EAC Code: 14



The use of the UKAS Accreditation Mark indicates accreditation to national or international standards managed by the accreditation certificate number 013 issued by NQA.  
NQA is a trading division of NQA Group Ltd, Registered No. 02701745. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Bedfordshire, LU5 5QJ.  
This certificate is the property of NQA and must be returned on request.





global assurance

This is to certify that the Quality Management System of

**Super Safe Plastic Products Co., Ltd.**

Meng Er Village, Pingshan County, Shijiazhuang, Hebei Province, China

applicable to

**Production and sales of disposable PVC surgical examination gloves**

has been assessed and registered by NQA against the provisions of  
**ISO 13485: 2003**

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.  
Please consult the website: [www.shqa.com.cn](http://www.shqa.com.cn)

Certification Director



015

Certificate Number **29113**

Date: 13 September 2013

Valid Until: 13 September 2016

EAC Code: 14



## TEST REPORT

Revised report.

Report No. : CH:TX:9420047919-1

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  
POWDER FREE BLUE NITRILE EXAMINATION  
**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 - 2                  |
|                        | 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](mailto:Feedback.SLT@sgs.com)

Test report revised to correct the thickness.

This report cancels and supersedes report no. 9420047919 Dated 29/09/2018 issued by SGS India

JOE No. : 1842825468

Page 1 of 4

Control No.:9425051386

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Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only. This document cannot be reproduced except in full, without prior approval of the Company.



**TEST REPORT**

Revised report.

**Report No. : CH:TX:9420047919-1****DATE : 09/10/2018****R E S U L T S****EN 420 : 2003+A1: 2009 Protective Gloves – General requirements and test methods**

| Clause | Test Name   | Result |     |       |   | Average | Standard sizing        |
|--------|---|--------|-----|-------|---|---------|------------------------|
| 5.1    | Sizing<br>Declared size XS<br>Circumference (mm)<br>Length (mm) | 160    | 162 | 161.0 |   | 292.0   | 6                      |
|        | Declared size S<br>Circumference (mm)<br>Length (mm)            | 174    | 172 | 173.0 |   | 287.5   | 6½                     |
|        | Declared size M<br>Circumference (mm)<br>Length (mm)            | 200    | 203 | 201.5 |   | 291.5   | 7½                     |
|        | Declared size L<br>Circumference (mm)<br>Length (mm)            | 220    | 224 | 222.0 |   | 288.5   | 8½                     |
|        | Declared size XL<br>Circumference (mm)<br>Length (mm)           | 240    | 236 | 238.0 |   | 300.5   | 9                      |
| 5.2    | Dexterity<br>Smallest Pin Diameter (mm)                         | 5      | 5   | 5     | 5 | 5       | Performance level<br>5 |

**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<br>(Air Pressure Used : 0.5 kPa) | <b>Specimen #</b> | <b>Leakage</b> | Pass              |
|        |  | Size XS           | No Leakage     |                   |
|        |  | Size S            | No Leakage     |                   |
|        |  | Size M            | No Leakage     |                   |
|        |  | Size L            | No Leakage     |                   |
| 4.2    | Water leak test                                | Size XL           | No Leakage     | Pass              |
|        |  | <b>Specimen #</b> | <b>Leakage</b> |                   |
|        |  | 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**

Revised report.

**Report No. : CH:TX:9420047919-1****DATE : 09/10/2018****RESULTS****pH VALUE**

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

Extraction Solution : KCL

**GLOVES – BLUE**

Value

6.6

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<br>CAS NO                      | Loop<br>system/collection<br>medium | Analytical<br>technique<br>used                                | Mean<br>thickness<br>(mm) | NBT at NPR<br>1.0 $\mu\text{cm}^{-2}$<br>min <sup>-1</sup><br>(minutes) | Performance<br>level<br>accordance to<br>EN ISO 374-1:<br>2016 Table 1 | Observation                           |
|---|-------------------------------------|--|---------------------------|---|--|---------------------------------------|
| Methanol<br>67-56-1                     | Open loop/<br>Nitrogen              | Continuous<br>measurement<br>With<br>GC-FID                    | 0.10<br>0.09<br>0.10      | <1<br><1<br><1  | Level - 0  | Moderate<br>swelling                  |
| Toluene<br>108-88-3                     | Open loop/<br>Nitrogen              | Continuous<br>measurement<br>With<br>GC-FID                    | 0.10<br>0.09<br>0.10      | <1<br><1<br><1  | Level - 0  | Severe<br>swelling                    |
| Diethylamine<br>109-89-7                | Open loop/<br>Nitrogen              | Continuous<br>measurement<br>With PID                          | 0.10<br>0.10<br>0.09      | <1<br><1<br><1  | Level - 0  | Severe<br>swelling                    |
| n-Heptane<br>142-85-5                   | Open loop/<br>Nitrogen              | Continuous<br>measurement<br>With<br>GC-FID                    | 0.09<br>0.10<br>0.10      | 32<br>33<br>35  | Level - 2  | Slight<br>swelling                    |
| Sodium<br>hydroxide<br>40%<br>1310-73-2 | Closed loop/<br>Grade 3 water       | Continuous<br>measurement<br>With<br>Conductivity<br>electrode | 0.10<br>0.09<br>0.09      | > 480<br>> 480<br>> 480   | Level - 6  | No change                             |
| Sulphuric acid<br>96%<br>7664-93-9      | Closed loop/<br>Grade 3 water       | Continuous<br>measurement<br>With<br>Conductivity<br>electrode | 0.09<br>0.10<br>0.09      | 5<br>5<br>4   | Level - 0  | Severe<br>swelling &<br>colour change |

\*\*\*\*\* End of page\*\*\*\*\*

JOE No. : 1842825468

Page 3 of 4

Control No.:9425051386

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Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only. This document cannot be reproduced except in full, without prior approval of the Company.



## TEST REPORT

Revised report.

Report No. : CH:TX:9420047919-1

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<br>Percentage change in puncture resistance |                   | Observation          |
|--------------------------------------|-------------------|--|-------------------|----------------------|
| Methanol<br>67-56-1                  | 60±5 minutes      | <u>Glove sample</u>                                      | <u>Result (%)</u> | Severe swelling      |
|                                      |                   | 1  | 78.9              |                      |
|                                      |                   | 2  | 79.3              |                      |
|                                      |                   | 3  | 79.4              |                      |
|                                      |                   | Mean   | 79.2              |                      |
|                                      |                   | Standard Deviation                                       | 0.245             |                      |
| Toluene<br>108-88-3                  | 60±5 minutes      | <u>Glove sample</u>                                      | <u>Result (%)</u> | Severe swelling      |
|                                      |                   | 1  | 79.4              |                      |
|                                      |                   | 2  | 77.7              |                      |
|                                      |                   | 3  | 79.6              |                      |
|                                      |                   | Mean   | 78.9              |                      |
|                                      |                   | Standard Deviation                                       | 1.004             |                      |
| Diethylamine<br>109-89-7             | 60±5 minutes      | <u>Glove sample</u>                                      | <u>Result (%)</u> | Severe swelling      |
|                                      |                   | 1  | 91.8              |                      |
|                                      |                   | 2  | 92.6              |                      |
|                                      |                   | 3  | 91.2              |                      |
|                                      |                   | Mean   | 91.8              |                      |
|                                      |                   | Standard Deviation                                       | 0.713             |                      |
| n-Heptane<br>142-85-5                | 60±5 minutes      | <u>Glove sample</u>                                      | <u>Result (%)</u> | Moderate swelling    |
|                                      |                   | 1  | 42.2              |                      |
|                                      |                   | 2  | 33.9              |                      |
|                                      |                   | 3  | 32.2              |                      |
|                                      |                   | Mean   | 36.1              |                      |
|                                      |                   | Standard Deviation                                       | 5.332             |                      |
| Sodium hydroxide<br>40%<br>1310-73-2 | 60±5 minutes      | <u>Glove sample</u>                                      | <u>Result (%)</u> | No change            |
|                                      |                   | 1  | -4.3              |                      |
|                                      |                   | 2  | -18.4             |                      |
|                                      |                   | 3  | -12.4             |                      |
|                                      |                   | Mean   | -11.7             |                      |
|                                      |                   | Standard Deviation                                       | 7.075             |                      |
| Sulphuric acid<br>96%<br>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\*\*\*\*\*





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

June 18, 2015

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

Re: K150340

Trade/Device Name: POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)

Regulation Number: 21 CFR 880.6250

Regulation Name: NITRILE Patient Examination Gloves (Power Free)

Regulatory Class: I

Product Code: LZA

Dated: May 14, 2015

Received: May 18, 2015

Dear Mr. Wang:

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

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



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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Erin I. Keith, M.S.  
Division Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 25, 2013

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

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

Dear Mr. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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



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

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

Sincerely yours,



Richard C.  
Chapman for

Kwame Ulmer M.S.  
Acting Division Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



**Indications for Use**

510(k) Number (if known)

K131440

Device Name

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

Indications for Use (Describe)

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

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

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 807 Subpart C)

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

**FOR FDA USE ONLY**

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



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Elizabeth F. Claverie  
2013.09.25 14:04:24 -04'00'





2013-2014

## CERTIFICATE OF REGISTRATION

This Certifies that

**HEBEI HONGSEN PLASTICS TECHNOLOGY CO., LTD**

Eastern industrial accumulation area, , Nangong

Xingtai, Hebei, 051800, CHINA

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

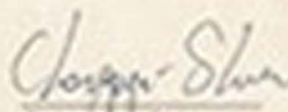
Owner Operator Number: [REDACTED]

| Listing Number | Product Code(s) | 510k Number | Device Name                       |
|----------------|-----------------|-------------|-----------------------------------|
| [REDACTED]     | LZA             | K131440     | Polymet patient examination glove |

Date of verification: 2013-11-05

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

Manton Business and Technology Services  
New Jersey, USA

  
Cheng Shen  
Director  
11-05-2013

FDA



| 克重     | 美标 US |        |       |                |      |        |          |                      |
|--------|-------|--------|-------|----------------|------|--------|----------|----------------------|
| 9"3.0g | Size  | Length | Width | Thickness (mm) |      |        | 拉力 (Mpa) | 伸 <sup>?</sup> 率 (%) |
|        |       | (mm)   | (mm)  | Cuff           | Palm | Finger | ≥14      | ≥500%                |
|        | 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 | Width | Thickness (mm) |      |        | 拉力 (Mpa) | 伸 <sup>?</sup> 率 (%) |
|        |       | (mm)   | (mm)  | 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 | Width | Thickness (mm) |      |        | 拉力 (Mpa) | 伸 <sup>?</sup> 率 (%) |
|        |       | (mm)   | (mm)  | 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 | Width | Thickness (mm) |      |        | 拉力 (Mpa) | 伸 <sup>?</sup> 率 (%) |
|        |       | (mm)   | (mm)  | 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 | Width | Thickness (mm) |      |        | 拉力 (Mpa) | 伸 <sup>?</sup> 率 (%) |
|        |       | (mm)   | (mm)  | 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   |          |                      |
|        |       |        |       |                |      |        |          |                      |



| 克重     | 欧标 EU |        |       |                |      |        |          |           |
|--------|-------|--------|-------|----------------|------|--------|----------|-----------|
| 9"3.0g | Size  | Length | Width | Thickness (mm) |      |        | 拉力 (N)   | 伸[?]率 (%) |
|        |       | (mm)   | (mm)  | Cuff           | Palm | Finger | ≥6       | ≥500%     |
|        | XS    | 240    | 75±3  | 0.05           | 0.06 | 0.08   | 4.0-6.4  | 450-500   |
|        | S     | 240    | 85±3  | 0.05           | 0.06 | 0.08   |          |           |
|        | M     | 240    | 95±3  | 0.05           | 0.06 | 0.08   |          |           |
|        | L     | 240    | 105±3 | 0.05           | 0.06 | 0.08   |          |           |
|        | XL    | 240    | 115±3 | 0.05           | 0.06 | 0.08   |          |           |
| 9"3.5g | Size  | Length | Width | Thickness (mm) |      |        | 拉力 (N)   | 伸[?]率 (%) |
|        |       | (mm)   | (mm)  | Cuff           | Palm | Finger | ≥6       | ≥500%     |
|        | XS    | 240    | 75±3  | 0.06           | 0.07 | 0.09   | 4.3-6.8  | 500-520   |
|        | S     | 240    | 85±3  | 0.06           | 0.07 | 0.09   |          |           |
|        | M     | 240    | 95±3  | 0.06           | 0.07 | 0.09   |          |           |
|        | L     | 240    | 105±3 | 0.06           | 0.07 | 0.09   |          |           |
|        | XL    | 240    | 115±3 | 0.06           | 0.07 | 0.09   |          |           |
| 9"4.0g | Size  | Length | Width | Thickness (mm) |      |        | 拉力 (N)   | 伸[?]率 (%) |
|        |       | (mm)   | (mm)  | Cuff           | Palm | Finger | ≥6       | ≥500%     |
|        | XS    | 240    | 75±3  | 0.06           | 0.07 | 0.10   | 6.9-8.4  | 500-540   |
|        | S     | 240    | 85±3  | 0.06           | 0.07 | 0.10   |          |           |
|        | M     | 240    | 95±3  | 0.06           | 0.07 | 0.10   |          |           |
|        | L     | 240    | 105±3 | 0.06           | 0.07 | 0.10   |          |           |
|        | XL    | 240    | 115±3 | 0.06           | 0.08 | 0.10   |          |           |
| 9"4.5g | Size  | Length | Width | Thickness (mm) |      |        | 拉力 (N)   | 伸[?]率 (%) |
|        |       | (mm)   | (mm)  | Cuff           | Palm | Finger | ≥6       | ≥500%     |
|        | XS    | 240    | 75±3  | 0.08           | 0.10 | 0.11   | 4.5-10.2 | 500-540   |
|        | S     | 240    | 85±3  | 0.08           | 0.10 | 0.11   |          |           |
|        | M     | 240    | 95±3  | 0.08           | 0.10 | 0.11   |          |           |
|        | L     | 240    | 105±3 | 0.08           | 0.10 | 0.11   |          |           |
|        | XL    | 240    | 115±3 | 0.08           | 0.10 | 0.11   |          |           |
| 9"4.8g | Size  | Length | Width | Thickness (mm) |      |        | 拉力 (N)   | 伸[?]率 (%) |
|        |       | (mm)   | (mm)  | Cuff           | Palm | Finger | ≥6       | ≥500%     |
|        | XS    | 240    | 75±3  | 0.09           | 0.10 | 0.11   | 6.0-11.4 | 500-530   |
|        | S     | 240    | 85±3  | 0.09           | 0.10 | 0.11   |          |           |
|        | M     | 240    | 95±3  | 0.09           | 0.10 | 0.11   |          |           |
|        | L     | 240    | 105±3 | 0.09           | 0.10 | 0.11   |          |           |
|        | XL    | 240    | 115±3 | 0.09           | 0.10 | 0.11   |          |           |