

# VELVET GRIP

Disposable NITRILE GLOVES



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## CERTIFICATIONS

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## MANUFACTURING ACCREDITATIONS

### ISO 9001: 2015



## MANUFACTURING ACCREDITATIONS

### ISO 13485:2016



**Certificate**

**Quality Management System**  
EN ISO 13485:2016

Registration No.: SX 2059694-1

Organization: Zhonghong Pulin Medical Products Co., Ltd.  
West Industrial Park, Luannan County, Tangshan City,  
063500 Hebei, P.R. China

Scope: Design and Development, Manufacture and Distribution of Patient Examination Gloves

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190131115 110  
Effective date: 2021-04-15  
Expiry date: 2024-04-14  
Issue date: 2021-04-13

TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

**DAKKS**  
Sachverständigenbüro  
D-90431 Nürnberg

**APPROVED BY GGL**



**Certificate**

**Quality Management System**  
EN ISO 13485:2016

Registration No.: SX 2059694-1

Organization: Zhonghong Pulin Medical Products Co., Ltd.  
West Industrial Park, Luannan County, Tangshan City,  
063500 Hebei, P.R. China

The scope of certification also covers the following:

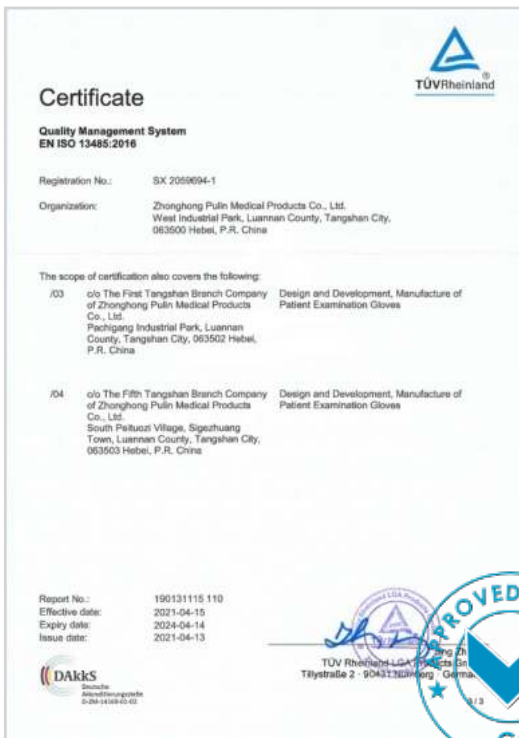
No.	Facility	Scope
/01	c/o Zhonghong Pulin Medical Products Co., Ltd. West Industrial Park, Luannan County, Tangshan City, 063500 Hebei, P.R. China	Distribution of Patient Examination Gloves
/02	c/o Minghao Medical Products Co., Ltd. West Industrial Park, Luannan County, Tangshan City, 063500 Hebei, P.R. China	Design and Development, Manufacture of Patient Examination Gloves

Report No.: 190131115 110  
Effective date: 2021-04-15  
Expiry date: 2024-04-14  
Issue date: 2021-04-13

TÜV Rheinland LGA Products GmbH  
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**Certificate**

**Quality Management System**  
EN ISO 13485:2016

Registration No.: SX 2059694-1

Organization: Zhonghong Pulin Medical Products Co., Ltd.  
West Industrial Park, Luannan County, Tangshan City,  
063500 Hebei, P.R. China

The scope of certification also covers the following:

/03	c/o The First Tangshan Branch Company of Zhonghong Pulin Medical Products Co., Ltd. Piaohang Industrial Park, Luannan County, Tangshan City, 063502 Hebei, P.R. China	Design and Development, Manufacture of Patient Examination Gloves
/04	c/o The Fifth Tangshan Branch Company of Zhonghong Pulin Medical Products Co., Ltd. South Peiluan Village, Sigeshuang Town, Luannan County, Tangshan City, 063503 Hebei, P.R. China	Design and Development, Manufacture of Patient Examination Gloves

Report No.: 190131115 110  
Effective date: 2021-04-15  
Expiry date: 2024-04-14  
Issue date: 2021-04-13

TÜV Rheinland LGA Products GmbH  
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**Business Stream Products**  
Certification Department

**TÜV Rheinland LGA**  
Precisely Right.

TÜV Rheinland LGA Products GmbH • 91109 KSCN

Company:  
TUV 440 811 002 0225  
MW Service  
GBL-Team  
Date: April 10, 2021

Organization:  
Zhonghong Pulin Medical Products Co., Ltd.  
West Industrial Park, Luannan County, Tangshan City,  
063500 Hebei, P.R. China

Application for: **QMS**  
Certificate No.: SX 2059694-1  
Requirement : EN ISO 13485:2016

Dear Madam or Sir,  
Enclosed please find the new certificate No. SX 2059694-1 replacing the previous certificate.  
With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,  
  
Jing Zhang  
Certification body

TÜV Rheinland LGA Products GmbH  
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Chairman of the Supervisory Board:  
Dr.-Ing. Ralf Schneider

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## INTERNATIONAL STANDARDS

### EN 455:1-4

**Test Report No. 7191240823-EEC20/01-LDY**  
dated 20 Oct 2020



Note: This report is issued subject to the Testing and Certification Regulations of the TUV SUD Group and the General Terms and Conditions of Business of TUV SUD Group AG. In addition, the report is governed by the IVDs Act and/or its updates.

**SUBJECT:**  
Testing of Gloves submitted by Zhonghong Pulin Medical Products Co., Ltd. on 21 Jul 2020.

**TESTED FOR:**  
Zhonghong Pulin Medical Products Co., Ltd.  
West Industrial Park,  
Luzhuan County,  
Tangshan City, China.

**TEST DATE:**  
22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

**DESCRIPTION OF SAMPLES:**

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue	20200426	S	400	Zhonghong Pulin Medical Products Co., Ltd.

Lot size as specified by client: 150,501 to 300,500 pieces

**METHOD OF TEST:**

- EN 455-1:2020 Medical gloves for single use Part 1: Requirements and testing for freedom from holes
- EN 455-2:2015 Medical gloves for single use Part 2: Requirements and testing for physical properties
- EN 455-3:2015 Medical glove for single use Part 3: Requirements and testing for biological evaluation
  - Clause 4.4 Powder-free gloves
  - Clause 4.6 Labeling





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TUV<sup>®</sup>

**Test Report No. 7191240823-EEC20/01-LDY**  
dated 20 Oct 2020



**RESULTS:**  
Sample: Nitrile Disposable Exam Gloves, Lot No. 20200426, Blue, Size S

**Table 1: Results for EN 455-1:2020**


Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers (found) (pieces)	Inferred results
4	Freedom from holes	Shall not leak	10	315	0	Passed

**Table 2: Results for EN 455-2:2015 Clauses 4.4**


Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	a) Dimensions (J/width) (mm)	≥ 240	13	246	Passed
	b) Width (mm)	For Size S (60-70)	13	83	Passed
5	a) Strength (N)	For nitrile examination gloves: ≥ 6.0	13	7.6	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	7.4	Passed

**Table 3: Results for EN 455-3:2015 Clause 7**

Clause	Tests	Requirements	Results	Inferred results
7	Labeling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1541:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed



**Test Report No. 7191240823-EEC20/01-LDY**  
dated 20 Oct 2020




**RESULTS (cont'd):**  
Sample: Nitrile Disposable Exam Gloves, Lot No. 20200426, Blue, Size S

**Table 4: Results for EN 455-3:2015 Clause 4.4**

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.52 mg per glove	Passed

**Table 5: Results for EN 455-3:2015 Clause 4.6**

Clause	Tests	Requirements	Results
4.6	Labeling	In addition to the labeling specified in EN 1541:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labeled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex. The labeling shall include the following or equivalent warning statement together with the symbol: "(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses."	NA
		b) the labeling shall include a prominent indication of whether the glove is powdered or powder-free.	Comply
		c) sterile powdered gloves shall be labeled with the following or equivalent: "CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions."	NA
		d) for any medical glove containing natural rubber latex the product labeling shall not include: <ul style="list-style-type: none"> <li>any term suggesting relative safety, such as low sterility, hypoallergenicity or low protein</li> <li>any unqualified indication of the presence of allergens.</li> </ul>	NA
e) if the manufacturer labels the gloves with the protein content, the protein limit, measured as specified in 6.3, shall be given.	NA		
		Inferred results	Passed



**Test Report No. 7191240823-EEC20/01-LDY**  
dated 20 Oct 2020



**REMARKS:**

- Labeling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
- NA: Not applicable for the submitted sample.

Yao Poh Kwang  
Associate Engineer

Lee Chi Yi  
Engineer  
Medical Health Services (NAM)

**APPENDIX:**




Photo 1: Nitrile Disposable Exam Gloves, Lot No. 20200426, Blue

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200426, Blue



## INTERNATIONAL STANDARDS

### EN 455:1-4

**Test Report No. 7191240823-EEC20/01-LDY**  
dated 20 Oct 2020




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

- This report applies to the sample of the specific production/shipment given at the time of its homologation. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SUD PSE approves, recommends or endorses the manufacturer, supplier or user of such production/shipment, or that TÜV SUD PSE in any way "guarantees" the later performance of the production/shipment. Unless otherwise stated in this report, no tests were conducted to determine long-term effects of using the specific production/shipment.
- The samples mentioned in this report shall be submitted to the manufacturer by the Client. TÜV SUD PSE therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, composition or any information supplied.
- Nothing in this report shall be interpreted to mean that TÜV SUD PSE has verified or ascertained any endorsement or marks from any other testing authority or other test results for these or other samples.
- This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SUD PSE or to the report or results furnished by TÜV SUD PSE in any advertisements or sales promotion.
- Unless otherwise stated, the tests were carried out in TÜV SUD PSE Pse (M, No. 1) Selegier Park Drive Singapore 116271.
- The tests carried out by TÜV SUD PSE and this report are subject to TÜV SUD PSE's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SUD Group.

Effective 01 September 2020




**Test Report No. 7191240823-EEC20/02-LDY**  
dated 20 Oct 2020



**Note:** This report is issued subject to the Testing and Certification Regulations of the TÜV SUD Group and the General Terms and Conditions of Business of TÜV SUD PSE Pse (M, No. 1) in addition, this report is governed by the terms set out within this report.

**SUBJECT:**  
Testing of Gloves submitted by Zhonghong Pulin Medical Products Co., Ltd. on 21 Jul 2020.

**TESTED FOR:**  
Zhonghong Pulin Medical Products Co., Ltd.  
West Industrial Park,  
Luzhuan County,  
Tangshan City, China

**TEST DATE:**  
22 Jul 2020 to 14 Aug 2020, 00 Oct 2020

**DESCRIPTION OF SAMPLES:**

S/N	Product Description	Colour	Lot No.	Size	Sample required (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue	20200428	M 400		Zhonghong Pulin Medical Products Co., Ltd.

Lot size as specified by client: 100,000 to 500,000 pieces

**METHOD OF TEST:**

- EN 455-1:2020 Medical gloves for single use  
Part 1: Requirements and testing for freedom from holes
- EN 455-2:2016 Medical gloves for single use  
Part 2: Requirements and testing for physical properties
- EN 455-3:2016 Medical glove for single use  
Part 3: Requirements and testing for biological evaluation  
- Clause 4.4 Powder-free gloves  
- Clause 4.6 Labeling




Labeling: TÜV SUD PSE, Ltd. No. 1 Selegier Park Drive Singapore 116271

Phone: +65 6881 1555 Fax: +65 6776 8762 E-Mail: enquiry@tuv.com.sg Web: www.tuv.com.sg

Reported Test Office: TÜV SUD Asia Pacific Pte. Ltd. 1 Selegier Park Drive #02-01 Singapore 116271



**Test Report No. 7191240823-EEC20/02-LDY**  
dated 20 Oct 2020



**RESULTS:**  
Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size M

**Table 1: Results for EN 455-1:2020**

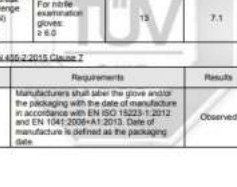

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4	Freedom from holes	Shall not leak	10	215	3	Passed

**Table 2: Results for EN 455-2:2016 Clauses 4.5**


Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	a) Length (mm)	≥ 240	13	240	Passed
	b) Width (mm)	For Size M: 95.5-100	13	93	Passed
5	a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	6.9	Passed
	b) Force at break after challenge testing (N) 7 days at 120°C/70%	For nitrile examination gloves: ≥ 6.0	13	7.1	Passed

**Table 3: Results for EN 455-3:2016 Clause 7**

Clause	Tests	Requirements	Results	Inferred results
7	Labeling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN ISO 15223-4:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

**Test Report No. 7191240823-EEC20/02-LDY**  
dated 20 Oct 2020





**RESULTS (cont'd):**  
Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size M

**Table 4: Results for EN 455-3:2016 Clause 6.4**

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4	Powder-free gloves	For powder-free gloves, the total quantity of powder residues shall not exceed 2 mg per glove.	1.08 mg per glove	Passed

**Table 5: Results for EN 455-3:2016 Clause 4.6**

Clause	Tests	Requirements	Results
4.6	Labeling	In addition to the labeling specified in EN ISO 15223-1:2012 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply: a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex. The labeling shall include the following or equivalent warning statement together with the symbol: "Product contains natural rubber latex which may cause allergic reactions, including anaphylactic reactions."	NA
		b) the labeling shall include a prominent indication of whether the glove is powdered or powder-free.	NA
		c) sterile powdered gloves shall be labelled with the following or equivalent: "CAUTION: Surface powder shall be removed meticulously prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions."	NA
		d) for any medical glove containing natural rubber latex the product labeling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unqualified indication of the presence of allergens.	NA
		e) if the manufacturer labels the gloves with the protein content, the protein limit, measured as specified in 5.3 shall be given.	NA
		Inferred results	Passed

## INTERNATIONAL STANDARDS

### EN 455:1-4

**Test Report No. 7191240823-EEC20/02-LDY**  
dated 20 Oct 2020



**REMARKS:**

- Labeling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
- NA: Not applicable for the submitted sample.

*Yeo Poh Kwang*  
Associate Engineer

*Zak Che Yi*  
Engineer  
Medical Health Services (NAM)

**APPENDIX:**



Photo 1: Nitrile Disposable Exam Gloves, Lot No. 20200426, Blue



Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200426, Blue



**Test Report No. 7191240823-EEC20/02-LDY**  
dated 20 Oct 2020



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- The accuracy mentioned in the report does not include the information provided by the Client. TUV SUD PSE PSE assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacturer, composition or any information supplied.
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- This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TUV SUD PSE or in the report or results furnished by TUV SUD PSE in any advertisements or sales promotion.
- Unless otherwise stated, the tests were carried out in TUV SUD PSE PSE Lab, No. 1 Science Park Drive, Singapore 118201.
- The tests carried out by TUV SUD PSE and this report are subject to TUV SUD PSE's General Terms and Conditions of Business and the Testing and Certification Regulations of the TUV SUD Group.

Effective 01 September 2020




**Test Report No. 7191240823-EEC20/03-LDY**  
dated 20 Oct 2020



Note: This report is issued under the Testing and Certification Regulations of the TUV SUD Group and the General Terms and Conditions of Business of TUV SUD PSE PSE Lab. In addition, this report is governed by the terms and conditions of this report.

**SUBJECT:**  
Testing of Gloves submitted by Zhonghong Pulin Medical Products Co., Ltd. on 21 Jul 2020.

**TESTED FOR:**  
Zhonghong Pulin Medical Products Co., Ltd.  
West Industrial Park,  
Luoman County,  
Tangshan City, China

**TEST DATE:**  
22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

**DESCRIPTION OF SAMPLES:**

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue	20200426	L	399	Zhonghong Pulin Medical Products Co., Ltd.

Lot size as specified by client: 150,500 to 500,000 pieces

**METHOD OF TEST:**

- EN 455-1:2020 Medical gloves for single use  
Part 1: Requirements and testing for freedom from holes
- EN 455-2:2015 Medical gloves for single use  
Part 2: Requirements and testing for physical properties
- EN 455-3:2015 Medical glove for single use  
Part 3: Requirements and testing for biological evaluation  
- Clause 4.4 Powder-free gloves  
- Clause 4.6 Labeling




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Page 1 of 2  
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Singapore 118201  
**TUV**

**Test Report No. 7191240823-EEC20/03-LDY**  
dated 20 Oct 2020



**RESULTS:**  
Sample: Nitrile Disposable Exam Gloves, Lot No. 20200426, Blue, Size L

**Table 1: Results for EN 455-1:2020**


Clause	Tests	Requirements	No. of non-compliers (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4	Freedom from holes	Shall not leak	10	315	3	Passed

**Table 2: Results for EN 455-2:2015 Clauses 4.5**

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	a) Length (mm)	≥ 240	13	243	Passed
	b) Width (mm)	For Size L: 105 ± 10	13	104	Passed
5	a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	7.5	Passed
	b) Force at break after challenge testing (N) 7 days at 125±2°C	For nitrile examination gloves: ≥ 6.0	13	8.1	Passed

**Table 3: Results for EN 455-2:2015 Clause 7**

Clause	Tests	Requirements	Results	Inferred results
7	Labeling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1061:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed




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Page 2 of 2  
**GGL**

## INTERNATIONAL STANDARDS

### EN 455:1-4

Test Report No. 7191240823-EEC20/03-LDY  
dated 20 Oct 2020



**RESULTS (cont'd):**


Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size L

**Table 4: Results for EN 455-2:2015 Clause 4.4**

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4	Powder-free gloves	For powder-free gloves, the total quantity of powder residues shall not exceed 2 mg per glove	0.96 mg per glove	Passed

**Table 5: Results for EN 455-3:2015 Clause 4.6**

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1541:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	NA
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex.	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: "Product contains natural rubber latex which may cause allergic reactions, including anaphylactic response."	Comply
		b) the labeling shall include a prominent indication of whether the glove is powdered or powder free.	NA
		c) sterile powdered gloves shall be labelled with the following or equivalent "CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions."	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: <ul style="list-style-type: none"> <li>- any terms suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein;</li> <li>- any unqualified indication of the presence of allergen;</li> </ul>	NA
e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA		
Inferred results			Passed



Test Report No. 7191240823-EEC20/03-LDY  
dated 20 Oct 2020



**REMARKS:**

- Labelling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
- NA: Not applicable for the submitted sample.

Yeo Pui Kwang Associate Engineer  
Loi GM Yi Engineer Medical Health Services (NAM)

**APPENDIX:**



Photo 1: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue



Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue



Test Report No. 7191240823-EEC20/03-LDY  
dated 20 Oct 2020



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- This report applies to the sample of the specific production/shipment given at the time of its homologation. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD approves, recommends or endorses the manufacturer, supplier or user of such production/shipment, or that TÜV SÜD PSE in any way "guarantees" the later performance of the production/shipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific production/shipment.
- The samples mentioned in this report were submitted/applied/manufactured by the Client. TÜV SÜD PSE therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, assignment or any information supplied.
- Nothing in this report shall be interpreted to mean that TÜV SÜD PSE has verified or ascertained any environment or risks from any other testing authority or bodies that may be based on that sample.
- This report shall not be reproduced wholly or in parts and no alterations shall be made by the Client to TÜV SÜD PSE or to the report or results furnished by TÜV SÜD PSE in any advertisements or sales promotion.
- Unless otherwise stated, the tests were carried out in TÜV SÜD PSE (Pte Ltd), No. 1 Seletar Drive, Singapore 118271.
- The tests carried out by TÜV SÜD PSE and this report were subject to TÜV SÜD PSE's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 01 September 2023




Test Report No. 7191240823-EEC20/04-LDY  
dated 20 Oct 2020



**SUBJECT:**  
Testing of Gloves submitted by Zhonghong Pulin Medical Products Co., Ltd. on 21 Jul 2020.

**TESTED FOR:**  
Zhonghong Pulin Medical Products Co., Ltd.  
West Industrial Park,  
Luotian County,  
Tangshan City, China

**TEST DATE:**  
22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

**DESCRIPTION OF SAMPLES:**

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue	20200428	XL	401	Zhonghong Pulin Medical Products Co., Ltd.

Lot size as specified by client: 150,000 Pcs 500,000 pieces

**METHOD OF TEST:**

- EN 455-1:2020 Medical gloves for single use  
Part 1: Requirements and testing for freedom from holes
- EN 455-2:2015 Medical gloves for single use  
Part 2: Requirements and testing for physical properties
- EN 455-3:2015 Medical glove for single use  
Part 3: Requirements and testing for biological evaluation
  - Clause 4.4 Powder-free gloves
  - Clause 4.6 Labelling



Labouratory  
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Singapore 118271  
Incorporated in Germany  
TUV






## INTERNATIONAL STANDARDS

### EN 455:1-4

**Test Report No. 7191240823-EEC20/04-LDY**  
dated 20 Oct 2020



**RESULTS:**  
Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size XL

**Table 1: Results for EN 455-1:2020**


Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no of non-compliers found (pieces)	Inferred results
4	Freedom from holes	Shall not leak	10	315	2	Passed

**Table 2: Results for EN 455-2:2015 Clauses 4.1**


Clause	Tests	Requirements (Method)	Number tested (pieces)	Results (Method)	Inferred results
4	a) Length (mm)	≥ 240	13	249	Passed
	b) Width (mm)	For size XL: ≥ 110	13	114	Passed
5	a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	6.8	Passed
	b) Force at break after challenge testing (N) 7 days at 70±2°C	For nitrile examination gloves: ≥ 6.0	13	7.0	Passed

**Table 3: Results for EN 455-4:2015 Clause 7**

Clause	Tests	Requirements	Results	Inferred results
7	Labeling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2009+AT:2013. Date of manufacture is defined as the packaging date.	Observed	Passed



**Test Report No. 7191240823-EEC20/04-LDY**  
dated 20 Oct 2020




**RESULTS (cont'd):**  
Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size XL

**Table 4: Results for EN 455-3:2015 Clause 4.4**

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4	Powder-free gloves	For powder-free gloves, the total quantity of powder residues shall not exceed 2 mg per glove.	0.64 mg per glove	Passed

**Table 5: Results for EN 455-3:2015 Clause 4.6**

Clause	Tests	Requirements	Results
4.6	Labeling	In addition to the labeling specified in EN 1041:2009+AT:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labeled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex.	NA
		The labeling shall include the following or equivalent warning statement together with the symbol: (product) contains natural rubber latex which may cause allergic reactions, including anaphylactic reactions.	NA
		b) the labeling shall include a prominent indication of whether the glove is powdered or powder-free.	Comply
		c) sterile powdered gloves shall be labeled with the following or equivalent: CAUTION: Surface powder shall be removed thoroughly prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions.	NA
d) for any medical glove containing natural rubber latex the product labeling shall not include:	NA		
- any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein;	NA		
- any unqualified indication of the presence of latex; or	NA		
e) if the manufacturer labels the gloves with the protein content, the protein limit, measured as specified in B.3 shall be given.	NA		
Inferred results			Passed



**Test Report No. 7191240823-EEC20/04-LDY**  
dated 20 Oct 2020



**REMARKS:**

- Labeling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
- NA: Not applicable for the submitted sample.

Yeo Poh Kwang  
Associate Engineer

SUN  
Zhang Yi  
Engineer  
Medical Health Services (M&M)

**APPENDIX:**



Photo 1: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue



Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue



**Test Report No. 7191240823-EEC20/04-LDY**  
dated 20 Oct 2020



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

- This report applies to the sample of the specific production given at the time of its registration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SUD PSE approves, recommends or endorses the manufacturer, supplier or user of such production, or that TÜV SUD PSE in any way guarantees the later performance of the production. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific production.
- The samples mentioned in the report were submitted/produced by the Client. TÜV SUD PSE therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, composition or any information supplied.
- Nothing in the report shall be interpreted to mean that TÜV SUD PSE has verified or re-verified any endorsement or marks from any other testing authority or bodies that may be found on that sample.
- This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SUD PSE or to the report as results furnished by TÜV SUD PSE in any advertisements or other materials.
- Unless otherwise stated, the tests were carried out in TÜV SUD PSE (Pte) Ltd, No. 1 Science Park Drive Singapore 118211.
- The tests carried out by TÜV SUD PSE and this report are subject to TÜV SUD PSE's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SUD Group.

Effective 01 September 2020




## INTERNATIONAL STANDARDS

### EN ISO 21420, EN ISO 374-2, EN 374-5



SATRA Technology Devices (Shanghai) Ltd  
Unit 110, Ansheng Garden, Xiang  
Nanping District, Dongguan City,  
Guangdong Province, China  
Tel: +86-755-78630000  
Email: ggl@curagrip.com

Customer details: Zhongheng Pulin Medical Products Co., Ltd.  
West Industrial Park, Luannan County  
Tangshan City  
Hebei  
China  
063500

SATRA reference: CHT030928 (2109)  
Your reference: ZHPFN02  
Date of report: 23 March 2021  
Samples received: 1 March 2021  
Date(s) work carried out: 4-22 March 2021


### TECHNICAL REPORT

Subject: EN ISO 21420: 2020 size & dexterity & innocuousness test, EN ISO 374-2: 2019 air leak and water leak, EN ISO 374-5: 2016 viruses on Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: blue, size: XS(S-6), S(6-7), M(7-8), L(8-9), XL(9-10)

**Conditions of issue:**  
This report may be forwarded to other parties provided that it is not changed in any way, it must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.  
Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.  
A satisfactory test result in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.  
The uncertainty of the result (LoM) in this report is based on a standard uncertainty multiplied by a coverage factor which provides a coverage probability of approximately 95%.

Report signed by: Gladys He  
Position: Technologist  
Department: China Testing


(Page 1 of 9)

### TECHNICAL REPORT

**WORK REQUESTED**  
Samples described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: blue, size: XS(S-6), S(6-7), M(7-8), L(8-9), XL(9-10) were received by SATRA on 1 March 2021 for testing in accordance with EN ISO 21420: 2020, EN ISO 374-2: 2019 and EN ISO 374-5: 2016.

**SAMPLE SUBMITTED**





Samples described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: blue

**TESTING REQUESTED**  
EN ISO 21420: 2020 Clause 5.1 – Sizing and measurement of gloves  
EN ISO 21420: 2020 Clause 5.2 – Dexterity  
EN ISO 374-2: 2019 Clause 7.2 – Air leak  
EN ISO 374-2: 2019 Clause 7.3 – Water leak  
EN ISO 374-5: 2016 Clause 5.3 – Protection against viruses (ISO 16604: 2004 Procedure B)  
EN ISO 21420: 2020 Clause 4.2 – Innocuousness of protective gloves

**CONCLUSION**  
The samples described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: blue, size: XS(S-6), S(6-7), M(7-8), L(8-9), XL(9-10) were found to achieve the following results:  
EN ISO 21420: 2020 Clause 5.1 – See below table  
EN ISO 21420: 2020 Clause 5.2 – Level 5  
EN ISO 374-2: 2019 Clause 7.2 – Pass  
EN ISO 374-2: 2019 Clause 7.3 – Pass  
EN ISO 374-5: 2016 Clause 5.3 – Pass  
EN ISO 21420: 2020 Clause 4.2 – Pass PAHs, pH value and DMF  
Detailed results are included on the following page(s)

Zhongheng Pulin Medical Products Co., Ltd.  
SATRA Reference: CHT030928 (2109)  
Date: 23 March 2021

(Page 2 of 9)

### TECHNICAL REPORT

**Testing**  
Testing was carried out in accordance with EN ISO 21420:2020 and EN ISO 374-2: 2019  
Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity.

**Requirements**  
Table 1 – Requirements for EN ISO 21420: 2020 Clause 5.2 Dexterity

Performance level	1	2	3	4	5
Diameter of dexterity pin /mm	11.0	9.5	8.0	6.5	5.0

Table 2 – Requirements for EN ISO 374-2: 2019



Clause 7.2 Air leak	No leak to be detected
Clause 7.3 Water leak	No leak to be detected

**Test Results**  
Table 3 – EN ISO 21420:2020 Test Results

Clause / Test	Requirement	Test Results	LoM (See note ●)	Result				
5.1 Glove length, comfort and fit	N/A	Size	Length /mm	± 1.10 mm	N/A			
		1	2			3		
		5-6	237			234	240	
		Comfortable on fit	6-7			230	235	236
		Comfortable on fit	7-8			246	245	240
		Comfortable on fit	8-9			237	235	240
		Comfortable on fit	9-10			254	258	260
5.2 Dexterity	See table 1	Size	Minimum pin diameter / mm	N/A	N/A			
		5-6	5.0					
		6-7	5.0					
		7-8	5.0					

Zhongheng Pulin Medical Products Co., Ltd.  
SATRA Reference: CHT030928 (2109)  
Date: 23 March 2021

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### TECHNICAL REPORT


Table 4 – EN ISO 374-2: 2019 Test Results

Clause / Test	Test Results	LoM (See note ●)	Result	
7.2 Air leak test	Total air pressure used	3.1 kPa	N/A	Pass
	Sample size	1 Leaks		
	5-6	No leaks detected		
	6-7	No leaks detected		
	7-8	No leaks detected		
7.3 Water leak test	Sample size	1 Leaks	N/A	Pass
	5-6	No leaks detected		
	6-7	No leaks detected		
	7-8	No leaks detected		
	8-9	No leaks detected		

**Additional Information / Notes**  
Note ● – Estimated uncertainty of measurement applied at point of test (e.g. to applied force or to tolerance limits) to ensure product meets requirements of the standard.

Zhongheng Pulin Medical Products Co., Ltd.  
SATRA Reference: CHT030928 (2109)  
Date: 23 March 2021

(Page 4 of 9)



## INTERNATIONAL STANDARDS

### EN ISO 21420, EN ISO 374-2, EN 374-5

### TECHNICAL REPORT

**Protection Against Viruses Test Results**

Testing was conducted at a third-party laboratory and reported under their reference 21R000882. The laboratory is CNAS accredited to ISO 17025: 2017 with ISO 18604: 2004 included in their accreditation schedule.

**Table 1 – Resistance to penetration by blood-borne pathogens results**

Test method	Specimen	Step 1 (8 kPa, 5 min)	Step 2 (14 kPa, 1min)	Step 3 (20 kPa, 4min)	Time of phage (PFU/mL)	Comment
ISO 15604:2004 Procedure B	1	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
Using rotating screen	2	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	3	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass

Zhongshong Pulin Medical Products Co., Ltd  
SATRA Reference: CHT0309328 (2109)  
Date: 23 March 2021

Signature:   
Chen Tingting

### TECHNICAL REPORT

**Innocuousness Test Results**

Testing was conducted at a third-party laboratory and reported under their reference A21004071001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
1001	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue	Gloves	-

**pH Value - EN ISO 21420:2020**

Test Method 1: With reference to EN ISO 4045:2018, analyzed by pH meter.  
Test Method 2: With reference to ISO 3071:2020, analyzed by pH meter.

Requirement	3.5.6.5
Test Results	Pass
Test Method	2
Parameters	-
pH Value of Immersion Solution	7.48
Temp. of Immersion Solution	25.1
pH Value of Aqueous Extract	7.4
Difference Signal	-
Conclusion	PASS

Note / Key: Temp. C = degree Celsius (°C), Temp. = Temperature  
Remark: Result(s) was (were) repeated the average value from two trials.

Zhongshong Pulin Medical Products Co., Ltd  
SATRA Reference: CHT0309328 (2109)  
Date: 23 March 2021

Signature:   
Chen Tingting

### TECHNICAL REPORT

**Polycyclic Aromatic Hydrocarbons (PAHs) Content - EN ISO 21420:2020**

Test Method: With reference to test method PQ-CEN ISO/TS 18190:2018

Maximum Allowable Limit:	Each of all listed PAHs: 1.0 mg/kg
--------------------------	------------------------------------

Tested Item(s)	Detected Analyte(s)	Conc.	Unit	Conclusion
1001	ND	ND	mg/kg	PASS

Note / Key: ND = Not detected (=Detection Limit) Detection Limit (mg/kg): Each: 0.2, mg/kg = milligram per kilogram = ppm = part per million

Remark: The list of polycyclic aromatic hydrocarbons is summarized in table of Appendix.

**APPENDIX**

No.	Name of Analytes	CAS-No.	No.	Name of Analytes	CAS-No.
1	Chrysene	218-01-8	5	Dibenz (a,h) anthracene	53-75-3
2	Benzo (a) pyrene	50-32-6	6	Benzo (b) fluoranthene	205-99-2
3	Benzo (a) pyrene	153-87-2	7	Benzo (k) fluoranthene	205-45-3
4	Benzo (a) anthracene	56-55-3	8	Benzo (g) hioxanthene	207-08-8

**Dimethylformamide (DMF) Content - EN ISO 21420:2020**

Test Method: With reference to EN 16778:2016, and then analyzed by Gas Chromatograph Mass Spectrometry

Analyte	Unit	Result	Client's Requirement
Dimethylformamide(DMF)	mg/kg	ND	1000
Conclusion	-	PASS	-

Note / Key: ND = Not detected (=Detection Limit) Detection Limit (mg/kg): 5, mg/kg = milligram per kilogram = ppm = part per million

\*\*\* End of Report \*\*\*

Zhongshong Pulin Medical Products Co., Ltd  
SATRA Reference: CHT0309328 (2109)  
Date: 23 March 2021

Signature:   
Chen Tingting

### TECHNICAL REPORT

**TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES**

- GENERAL**
  - When the customer places an order for the sale of goods or the provision of services, the customer agrees to be bound by the terms and conditions of sale set out in this report.
  - These terms and conditions apply to all orders placed with the supplier, whether the order is placed by a customer or by a third party.
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- DEFINITIONS**
  - Customer: The person or organization that places an order with the supplier.
  - Supplier: The person or organization that provides goods or services to the customer.
  - Order: A written or verbal instruction from the customer to the supplier to provide goods or services.
  - Invoice: A document issued by the supplier to the customer, detailing the goods or services provided and the amount due.
  - Payment: The amount of money paid by the customer to the supplier.
  - Delivery: The process of providing goods or services to the customer.
  - Acceptance: The process of the customer receiving and agreeing to the goods or services provided.
  - Dispute: A disagreement between the customer and the supplier.
  - Force Majeure: An event or circumstance that prevents the supplier from fulfilling its obligations.
  - Assignment: The transfer of rights or obligations from one party to another.
  - Entire Agreement: The complete and exclusive agreement between the parties.
  - Amendment: A change to the terms and conditions.
  - Waiver: The voluntary relinquishment of a right or claim.
  - Severability: The principle that if one part of a contract is invalid, the rest remains valid.
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  - Waiver: The voluntary relinquishment of a right or claim.
  - Severability: The principle that if one part of a contract is invalid, the rest remains valid.
- ORDER AND ACCEPTANCE**
  - Orders must be placed in writing and must specify the goods or services required, the quantity, and the delivery date.
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- DELIVERY**
  - The supplier warrants that the goods or services will be delivered in accordance with the order.
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- INVOICING**
  - The supplier will issue an invoice to the customer within 30 days of the date of delivery.
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- PAYMENT**
  - The customer must pay the invoice within 30 days of the date of issue.
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- ASSIGNMENT**
  - The customer cannot assign its rights or obligations under this report without the written consent of the supplier.
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- FORCE MAJEURE**
  - The supplier is not liable for any delay or non-delivery of goods or services caused by force majeure.
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- DISPUTE RESOLUTION**
  - Any dispute arising from this report shall be referred to arbitration.
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- ENTIRE AGREEMENT**
  - This report constitutes the entire agreement between the parties.
  - This report constitutes the entire agreement between the parties.
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- AMENDMENT**
  - Any amendment to this report must be made in writing and signed by both parties.
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- WAIVER**
  - The failure of either party to enforce any provision of this report shall not constitute a waiver of that provision.
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- SEVERABILITY**
  - If any provision of this report is held to be invalid or unenforceable, the remaining provisions shall remain in full force and effect.
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Zhongshong Pulin Medical Products Co., Ltd  
SATRA Reference: CHT0309328 (2109)  
Date: 23 March 2021

Signature:   
Chen Tingting



## INTERNATIONAL STANDARDS

### EN 374-1, EN 16523

**Customer details:** SATRA Technology Services (Dongguan) Ltd SATRA reference: CHM0314155/2122/LC  
 HONGWEI ROAD Your reference: CHT0313568  
 XIPING NANCHENG DISTRICT Date of report: 15<sup>th</sup> July 2021  
 DONGGUAN CITY Samples received: 1<sup>st</sup> June 2021  
 GUANGDONG PROVINCE Date's work carried out: 3<sup>rd</sup> June to 6<sup>th</sup> July 2021  
 CHINA  
 523079

### TECHNICAL REPORT

**SATRA Technology Services (Dongguan) Ltd:**  
 Customer: Zhongzhong Pulin Medical Products Co., Ltd.  
 West Industrial Park, Luoman County  
 Tangshan City  
 Hebei  
 China  
 063500

**Subject:** EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as ZHPFN02, colour: Blue.

**Conditions of Issue:**  
 This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.  
 Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.  
 Tests conducted fulfil exactly the UKAS Accreditation Schedule for SATRA.  
 All opinions and interpretations of results, and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.  
 A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.  
 Where values for uncertainty of measurement are included within the report then the uncertainty of the corresponding results are based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.  
 When reporting results against a conformance statement (Pass/Fail or the allocation of a class or level) then uncertainty of measurement is taken into account based on a non-dilatory procedure which shall be based on the greatest level being equal to the required uncertainty.  
 Where the result corrected for uncertainty falls within the tolerance of the conformance statement then the risk of the conformance statement being a false accept or false reject is up to 2.5% and SATRA will in this instance quote a Pass/Fail, class or level.  
 Where the result corrected for uncertainty falls outside of the tolerance of the conformance statement then the risk of the conformance statement being a false accept or false reject is up to 50%. In this instance SATRA will not provide a Pass/Fail statement or a class or level but will include information in the notes in relation to the result obtained.  
 Please note that where uncertainty of measurement values have not been included then uncertainty has not been applied to these results. SATRA uncertainty of measurement values are however available upon request.

Report signed by: Lucy Cove  
 Position: Technological  
 Department: Chemical & Analytical Technology  
 (Page 1 of 10)

SATRA Technology Centre Ltd is a subsidiary of SATRA. Registered in England No. 300268 at its own address.

### TECHNICAL REPORT

**WORK REQUESTED:**  
 Samples of gloves described as ZHPFN02, colour: Blue were received on the 1<sup>st</sup> June 2021 for testing in accordance with EN 16523-1:2015+A1:2018 and assessment in accordance with the requirements of EN ISO 374-1:2016+A1:2018.

**SAMPLES SUBMITTED:**

Samples described as ZHPFN02, colour: Blue.

**CONCLUSION:**  
 When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as ZHPFN02, colour: Blue achieved the following performance levels:

Chemical	Performance level
Methanol (CAS: 67-56-1)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
n-Heptane (CAS: 142-62-5)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
25% Ammonium hydroxide (CAS: 1336-21-6)	1
30% Hydrogen peroxide (CAS: 7722-84-1)	2

Full results are reported in the following tables

SATRA Technology Services (Dongguan) Ltd  
 SATRA Reference: CHM0314155/2122/LC  
 Date: 15<sup>th</sup> July 2021 (Page 2 of 10)

### TESTING REQUIRED:

- EN 16523-1:2015+A1:2018 - Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

**RESULTS AND REQUIREMENTS:**  
 EN ISO 374-1:2016+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels.

Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

Performance levels are based on the lowest individual result achieved per chemical.

SATRA Technology Services (Dongguan) Ltd  
 SATRA Reference: CHM0314155/2122/LC  
 Date: 15<sup>th</sup> July 2021 (Page 3 of 10)

### PERMEATION RATE GRAPHS


Challenge chemical: Methanol

Test/Property	Sample reference:	ZHPFN02, colour: Blue	Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-005	Test information:	Chemical: Methanol	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
		Normalised permeation rate (NPR): 1 µg/cm²min	
		Detection technique: GC-FID (periodic measurement)	
		Collection medium: Dry air (open loop)	
Specimen	Thickness (mm):	0.08	<1
		0.08	<1
		0.08	<1
Test result:		<1	
Visual appearance of specimens after testing		Swollen	


SATRA Technology Services (Dongguan) Ltd  
 SATRA Reference: CHM0314155/2122/LC  
 Date: 15<sup>th</sup> July 2021 (Page 4 of 10)

## INTERNATIONAL STANDARDS

### EN 374-1, EN 16523

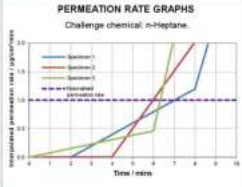


### TECHNICAL REPORT





Test/Property	Sample reference:	ZHPFN02, colour: Blue	Performance															
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-005  Using stainless steel permeation cells with standardised dimensions	<b>Test information:</b>	Chemical: n-Heptane	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved															
		Normalised permeation rate (NPR): 1 µg/cm <sup>2</sup> /min																
		Detection technique: GC-FID																
		Collection medium: Dry air (open loop)																
		Collection medium flow rate: 330 – 380 ml/min																
<b>Specimen</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Thickness (mm):</th> <th>Breakthrough time (mins)*</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>7</td> </tr> <tr> <td>2</td> <td>5</td> </tr> <tr> <td>3</td> <td>6</td> </tr> </tbody> </table>	Thickness (mm):	Breakthrough time (mins)*	1	7	2	5	3	6	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Thickness (mm):</th> <th>Breakthrough time (mins)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>0.05</td> </tr> <tr> <td>2</td> <td>0.07</td> </tr> <tr> <td>3</td> <td>0.07</td> </tr> </tbody> </table>	Thickness (mm):	Breakthrough time (mins)	1	0.05	2	0.07	3	0.07
		Thickness (mm):	Breakthrough time (mins)*															
		1	7															
2	5																	
3	6																	
Thickness (mm):	Breakthrough time (mins)																	
1	0.05																	
2	0.07																	
3	0.07																	
<b>Test result:</b>	UoM: <1																	
Visual appearance of specimens after testing:		Swollen																


**PERMEATION RATE GRAPHS**  
Challenge chemical: n-Heptane.




SATRA Technology Services (Dongguan) Ltd  
SATRA Reference: CHM0314155/2123LC  
Date: 15<sup>th</sup> July 2021 (Page 5 of 10)

Signed: 



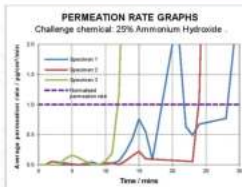


### TECHNICAL REPORT





Test/Property	Sample reference:	ZHPFN02, colour: Blue	Performance															
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009  Using PTFE permeation cells with standardised dimensions	<b>Test information:</b>	Chemical: 25% Ammonium hydroxide	Level 1															
		Normalised permeation rate (NPR): 1 µg/cm <sup>2</sup> /min																
		Detection technique: Conductivity																
		Collection medium: Deionised water (closed loop)																
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)																
<b>Specimen</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Thickness (mm):</th> <th>Breakthrough time (mins)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>19</td> </tr> <tr> <td>2</td> <td>24</td> </tr> <tr> <td>3</td> <td>12</td> </tr> </tbody> </table>	Thickness (mm):	Breakthrough time (mins)	1	19	2	24	3	12	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Thickness (mm):</th> <th>Breakthrough time (mins)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>0.05</td> </tr> <tr> <td>2</td> <td>0.05</td> </tr> <tr> <td>3</td> <td>0.06</td> </tr> </tbody> </table>	Thickness (mm):	Breakthrough time (mins)	1	0.05	2	0.05	3	0.06
		Thickness (mm):	Breakthrough time (mins)															
		1	19															
2	24																	
3	12																	
Thickness (mm):	Breakthrough time (mins)																	
1	0.05																	
2	0.05																	
3	0.06																	
<b>Test result:</b>	UoM: <1																	
Visual appearance of specimens after testing:		Swollen and discoloured																


**PERMEATION RATE GRAPHS**  
Challenge chemical: 25% Ammonium Hydroxide.




SATRA Technology Services (Dongguan) Ltd  
SATRA Reference: CHM0314155/2123LC  
Date: 15<sup>th</sup> July 2021 (Page 6 of 10)

Signed: 



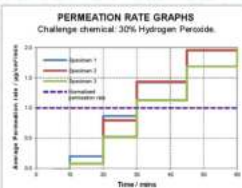


### TECHNICAL REPORT



Test/Property	Sample reference:	ZHPFN02, colour: Blue	Performance															
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025  Using PTFE permeation cells with standardised dimensions	<b>Test information:</b>	Chemical: 30% Hydrogen peroxide	Level 2															
		Normalised permeation rate (NPR): 1 µg/cm <sup>2</sup> /min																
		Detection technique: Electrochemical detector (periodic measurement)																
		Collection medium: Deionised water (closed loop)																
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)																
<b>Specimen</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Thickness (mm):</th> <th>Breakthrough time (mins)*</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Between 31 to 45</td> </tr> <tr> <td>2</td> <td>Between 31 to 45</td> </tr> <tr> <td>3</td> <td>Between 31 to 45</td> </tr> </tbody> </table>	Thickness (mm):	Breakthrough time (mins)*	1	Between 31 to 45	2	Between 31 to 45	3	Between 31 to 45	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Thickness (mm):</th> <th>Breakthrough time (mins)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>0.07</td> </tr> <tr> <td>2</td> <td>0.06</td> </tr> <tr> <td>3</td> <td>0.06</td> </tr> </tbody> </table>	Thickness (mm):	Breakthrough time (mins)	1	0.07	2	0.06	3	0.06
		Thickness (mm):	Breakthrough time (mins)*															
		1	Between 31 to 45															
2	Between 31 to 45																	
3	Between 31 to 45																	
Thickness (mm):	Breakthrough time (mins)																	
1	0.07																	
2	0.06																	
3	0.06																	
<b>Test result:</b>	UoM: See below																	
Visual appearance of specimens after testing:		Swollen and slightly discoloured																


**PERMEATION RATE GRAPHS**  
Challenge chemical: 30% Hydrogen Peroxide.




For SOP CAT-025, where both the P1 and Pu are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.

Hydrogen peroxide is determined by discrete sampling, therefore the permeation rate graph is not smooth curve.

SATRA Technology Services (Dongguan) Ltd  
SATRA Reference: CHM0314155/2123LC  
Date: 15<sup>th</sup> July 2021 (Page 7 of 10)

Signed: 





### TECHNICAL REPORT



EN 16523-1:2015+A1:2018 does not require the test specimen thicknesses to be reported, this information is indicative only.

- The collection medium from each cell is analysed once every 6 minutes. Due to the complexity of the detection technique, the minimum sampling frequency for final results ≤ 60 minutes as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible. Breakthrough time is calculated using linear interpolation between the discrete sampling points.
- Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible.

SATRA Technology Services (Dongguan) Ltd  
SATRA Reference: CHM0314155/2123LC  
Date: 15<sup>th</sup> July 2021 (Page 8 of 10)

Signed: 



## INTERNATIONAL STANDARDS

### EN 374-4




**SATRA Technology Centre Ltd**  
Wytham Way, Farnborough, Hampshire, SO24 0JQ, United Kingdom  
Tel: +44 (0) 1256 410000  
Fax: +44 (0) 1256 410008  
Email: info@satra.com  
www.satracentre.com

**Customer details:** SATRA Technology Services (Dongguan) Ltd SATRA reference: CHM0309851/2119L/C  
Unit 110, Xinchongqin Garden  
Hongwei Road  
Xiping, Nancheng District  
DONGGUAN CITY  
Guangdong Province  
China  
523078  
Your reference: CHT0309326  
Date of report: 28<sup>th</sup> April 2021  
Samples received: 07<sup>th</sup> March 2021  
Date(s) work carried out: 16<sup>th</sup> to 24<sup>th</sup> April 2021

### TECHNICAL REPORT



**SATRA Technology Services (Dongguan) Ltd:**  
Customer: Zhongheng Pain Medical Products Co. Ltd.  
West Industrial Park, Luannan County  
Tangshan City  
Hebei  
China  
063500

**Subject:** EN ISO 374-4:2019 determination of resistance to degradation by dangerous chemicals on gloves described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue

**Conditions of Issue:**  
This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.  
Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Conclusions are for guidance only.  
Tests marked # fall outside the UKAS Accreditation Schedule for SATRA.  
All opinions and interpretations of results, and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.  
A satisfactory test report to us implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in this report.  
Where values for uncertainty of measurement are included within the report then the uncertainty of the corresponding results are based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.  
When reporting results against a performance standard (Part 4) then uncertainty of measurement is taken into account based on a non-binary acceptance which itself is based on the guard band being equal to the expanded uncertainty.  
Where the result obtained for uncertainty on a worst-case basis falls outside of the requirement or specification then the risk of a pass result being a false success is up to 30%. We will therefore not provide other opinions or test statements when this occurs, but will include information in the notes in relation to the result obtained.  
Please note that where uncertainty of measurement values have not been included then uncertainty has not been applied to these results. SATRA uncertainty of measurement values are however available upon request.

Report signed by: Lucy Cowe  
Position: Technologist  
Department: Chemical & Analytical Technology  
(Page 1 of 6)


SATRA Technology Centre Ltd is a subsidiary of SATRA. Registered in England No. 3852661 at the above address.

### TECHNICAL REPORT

**WORK REQUESTED:**  
Samples of gloves described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue were received on the 07<sup>th</sup> March 2021 for testing in accordance with EN ISO 374-4:2019.

**SAMPLE SUBMITTED:**



Sample described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue.

**CONCLUSION:**  
When assessed in accordance with EN ISO 374-4:2019 the samples of gloves described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue achieved the following degradation results:

Chemical	Mean degradation / %
n-Heptane (CAS: 142-82-6)	49.3
30% Hydrogen peroxide (CAS: 7723-84-1)	34.1
25% Ammonium hydroxide (CAS: 1336-21-6)	41.2
40% Sodium hydroxide (CAS: 1310-73-2)	-8.3
37% Formaldehyde (CAS: 50-00-0)	34.3
Methanol (CAS: 67-56-1)	96.7

**TESTING REQUIRED:**

- EN ISO 374-4:2019. Protective gloves against dangerous chemicals and micro-organisms. Part 4. Determination of resistance to degradation by chemicals.

SATRA Technology Services (Dongguan) Ltd  
SATRA Reference: CHM0309851/2119L/C/B  
Date: 28<sup>th</sup> April 2021  
(Page 2 of 6)






### TECHNICAL REPORT

**RESULTS:**

<b>Sample description:</b>	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
<b>Challenge chemical:</b>	n-Heptane (CAS: 142-82-6)		
<b>Test temperature / °C:</b>	(23 ± 1)		
<b>Degradation / %:</b>	Glove 1	Glove 2	Glove 3
	47.8	54.1	46.1
<b>Mean degradation (DR) / %:</b>	49.3		
<b>Standard deviation (σ<sub>95</sub>) / %:</b>	4.2		
<b>UoM / ± %:</b>	14.2		
<b>Appearance of samples after testing:</b>	No change		

<b>Sample description:</b>	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
<b>Challenge chemical:</b>	30% Hydrogen peroxide (CAS: 7723-84-1)		
<b>Test temperature / °C:</b>	(23 ± 1)		
<b>Degradation / %:</b>	Glove 1	Glove 2	Glove 3
	21.9	37.1	43.3
<b>Mean degradation (DR) / %:</b>	34.1		
<b>Standard deviation (σ<sub>95</sub>) / %:</b>	11.0		
<b>UoM / ± %:</b>	12.1		
<b>Appearance of samples after testing:</b>	No change		

<b>Sample description:</b>	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
<b>Challenge chemical:</b>	25% Ammonium hydroxide (CAS: 1336-21-6)		
<b>Test temperature / °C:</b>	(23 ± 1)		
<b>Degradation / %:</b>	Glove 1	Glove 2	Glove 3
	48.0	56.6	18.8
<b>Mean degradation (DR) / %:</b>	41.2		
<b>Standard deviation (σ<sub>95</sub>) / %:</b>	19.8		
<b>UoM / ± %:</b>	13.1		
<b>Appearance of samples after testing:</b>	Swollen and discoloured		

SATRA Technology Services (Dongguan) Ltd  
SATRA Reference: CHM0309851/2119L/C/B  
Date: 28<sup>th</sup> April 2021  
(Page 3 of 6)






### TECHNICAL REPORT

<b>Sample description:</b>	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
<b>Challenge chemical:</b>	40% Sodium hydroxide (CAS: 1310-73-2)		
<b>Test temperature / °C:</b>	(23 ± 1)		
<b>Degradation / %:</b>	Glove 1	Glove 2	Glove 3
	-9.4	20.4	-35.9
<b>Mean degradation (DR) / %:</b>	-8.3		
<b>Standard deviation (σ<sub>95</sub>) / %:</b>	28.2		
<b>UoM / ± %:</b>	9.9		
<b>Appearance of samples after testing:</b>	Swollen		

<b>Sample description:</b>	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
<b>Challenge chemical:</b>	37% Formaldehyde (CAS: 50-00-0)		
<b>Test temperature / °C:</b>	(23 ± 1)		
<b>Degradation / %:</b>	Glove 1	Glove 2	Glove 3
	40.0	45.6	17.3
<b>Mean degradation (DR) / %:</b>	34.3		
<b>Standard deviation (σ<sub>95</sub>) / %:</b>	15.0		
<b>UoM / ± %:</b>	12.2		
<b>Appearance of samples after testing:</b>	Swollen		

<b>Sample description:</b>	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
<b>Challenge chemical:</b>	Methanol (CAS: 67-56-1)		
<b>Test temperature / °C:</b>	(23 ± 1)		
<b>Degradation / %:</b>	Glove 1	Glove 2	Glove 3
	98.5	96.9	94.5
<b>Mean degradation (DR) / %:</b>	96.7		
<b>Standard deviation (σ<sub>95</sub>) / %:</b>	2.0		
<b>UoM / ± %:</b>	See below*		
<b>Appearance of samples after testing:</b>	Swollen		

\*As a result of the low force required to puncture the specimen after degradation, this result is close to being outside the normal operating range of the tensile testing machine, hence that force is subject to a significant measurement uncertainty. However, this does not affect the overall result of the test as the degradation result for the specimen against the challenge chemical was very high.

**NOTE:** Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

SATRA Technology Services (Dongguan) Ltd  
SATRA Reference: CHM0309851/2119L/C/B  
Date: 28<sup>th</sup> April 2021  
(Page 4 of 6)



## REGULATION COMPLIANCE

CE 2777



**SATRA**  
TECHNOLOGICAL

Issued to:

Notified Body: 2777

SATRA customer number:

### EU Type-Examination Certificate

**Certificate number:**

The EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:  
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category II product.

<b>Product reference:</b>	<b>Description:</b>		
	Disposable Powder Free Nitrile Gloves.		
	Colour: Blue, Black		
<b>Sizes:</b>	<b>Classification:</b>	<b>Level</b>	<b>EN ISO 374-4:2019</b>
XS(S-6)	<b>EN ISO 374-1:2016+A1:2018/Type B</b>		<b>Degradation %</b>
S(S-7)	(K) Sodium hydroxide 40%	6	18.3
M(M-8)	(P) Hydrogen peroxide 30%	2	34.1
L(L-9)	(T) Formaldehyde 37%	4	34.3
XL(X-10)	<b>EN ISO 374-5:2016</b>	<b>Level</b>	
	Protection against Bacterial and Fungi	Pass	
	Protection against Viruses	Pass	

**Standards/Technical specifications applied:**  
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

**Technical reports/Approval documents:**  
SATRA:

Signed on behalf of SATRA:  Quirozy (Brown)

Date first issued: 26/08/2023  
Date of issue: 26/08/2023  
Expiry date: 26/08/2025



SATRA Technology Europe Limited, Stratford Business Park, Clonsilla, 21/07/2023, Results of testing



## INTERNATIONAL STANDARDS

### EN 1186

Test Report No.: 721645252-1  
Report Date: 11 April 2019

**SUBJECT** Chemical Test

**TEST LOCATION** TUV SUD China  
TUV SUD Products Testing (Shanghai) Co., Ltd.  
B-3/4, No. 1999 Du Hai Road, Minhang District  
Shanghai 201106, P.R. China

**CLIENT NAME** Zhonghong Pulin Medical Products Co., Ltd.  
**CLIENT ADDRESS** West Industrial Park, Luonan County, Tangshan City

**TEST PERIOD** 01-Mar-2019-08-Mar-2019

**TEST REQUEST** In accordance with Council of Europe Res AP (2004) 4

**CONCLUSION** **PASS**  
The submitted sample was found to comply with the overall migration requirement(s) as stated in European Resolution Res AP (2004) 4 on rubber to be used for food contact applications.

Prepared By: *Cynthia Cao*  
(Cynthia Cao)  
Report Drafter

Authorized By: *Lei Chen*  
(Lei Chen)  
Authorized Signatory

**APPROVED BY GGL**

Note: (1) General Terms & Conditions as mentioned elsewhere (2) The results relate only to the items tested (3) The test procedure is not to be used for any other purpose without the written approval of the laboratory (4) Without the agreement of the laboratory, the results of the test are not to be used for any other purpose.

Chemical/Biochemistry Laboratory  
TUV SUD Products Testing (Shanghai) Co., Ltd.  
B-3/4, No. 1999 Du Hai Road, Minhang District  
Shanghai  
201106  
P.R. China

Phone: +86 (21) 6221 6176  
Fax: +86 (21) 6221 6166  
Email: test@tuv-sud.cn  
Website: www.tuv-sud.cn

Regional Head Office  
TUV SUD Certification and Testing  
China Co., Ltd.  
No. 101, Hong Tong Road Shanghai  
200070, P.R. China

Page 1 of 2

Test Report No.: 721645252-1  
Report Date: 11 April 2019

**RECEIPT DATE / TEST DATE**  
01-Mar-2019/ 01-Mar-2019

**THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED BY/ ON BEHALF OF THE CLIENT(S) AS**

Sample Name: Powder free nitrile glove, blue  
Sample Specification: Medium  
Batch No./Date: 20190327  
Manufacturer: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721645252-1	Blue glove	

**TEST METHOD(S)**  
1. For material - Rubber  
- Overall migration test for compliance with European Resolution Res AP (2004) 4 on rubber to be used for food contact applications.  
- As specified in REGULATION (EU) No 1002/11 and its amendments, with reference to EN 1186: Part 2 (Test methods for overall migration into olive oil by total immersion) / EN 1186: Part 3 (Test methods for overall migration into aqueous food simulants by total immersion) / EN 1186: Part 14 (substitute test).

**TEST RESULT(S)**  
1. Overall Migration Test - with reference to EN 1186: Part 2, Part 3 & Part 14

Simulant(s) Used	Test Condition	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
10% Ethanol	70 °C for 2 hours	<5.0	60
3% Acetic acid	70 °C for 2 hours	<5.0	60
95% Ethanol	60 °C for 2 hours	<5.0	60
iso-octane	40 °C for 0.5 hour	<5.0	60

Note: 1. mg/kg denotes milligram per kilogram foodstuff  
2. Specification is quoted from European Resolution Res AP (2004) 4 on rubber to be used for food contact applications  
3. < denotes less than

Note: This report is for internal use only by the client.

-END OF THE TEST REPORT-

Chemical/Biochemistry Laboratory  
TUV SUD Products Testing (Shanghai) Co., Ltd.  
B-3/4, No. 1999 Du Hai Road, Minhang District  
Shanghai  
201106  
P.R. China

Phone: +86 (21) 6221 6176  
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Regional Head Office  
TUV SUD Certification and Testing  
China Co., Ltd.  
No. 101, Hong Tong Road Shanghai  
200070, P.R. China

Page 2 of 2

**APPROVED BY GGL**

## REGULATION COMPLIANCE

### FDA 510K

**510(k) Premarket Notification**

Device Classification: Polymer Patient Examination Glove

510(k) Number: K171873

Device Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non Sterile, Tested For Use With Chemotherapy Drugs

Applicant: Zhonghong Pulin Medical Products Co., Ltd. (Zhonghong Industrial Park, Luonan County, Tangshan, CN 063002)

Applicant Contact: Jing Li

Correspondent: Zhonghong Pulin Medical Products Co., Ltd. (800 - 10 Four Seasons Place, Toronto, CA M8S 9H7)

Correspondent Contact: Da Shi

Regulation Number: 883.8220

Classification Product Code: L24

Subsequent Product Code: L24

Date Received: 06/23/2017

Decision Date: 11/15/2017

Decision: Substantially Equivalent (SESE)

Regulation Medical Specialty: General Hospital

510k Reviewer Panel: General Hospital

Summary Panel: Summary

Type: Traditional

Reviewed By Third Party No: No

Combination Product: No

Page Last Updated: 06/28/2021

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October 15, 2017

**Zhonghong Pulin Medical Products Co., Ltd.**  
Da Shi  
Manager  
Zhonghong Pulin Medical Products Co., Ltd.  
800 - 10 Four Seasons Place  
Toronto, M9D 6H7, CA

Re: K171873  
Trade/Device Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non Sterile, Tested for Use with Chemotherapy Drugs  
Regulation Number: 21 CFR 803.8250  
Regulation Name: Patient Examination Glove  
Regulatory Class: Class II  
Product Code: L24/L24  
Dated: October 13, 2017  
Received: October 13, 2017

Dear Da Shi:

We have reviewed your September 10, 2017 premarket notification to market the device referenced above and have determined that your device is substantially equivalent to 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, at your discretion, 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 below) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls beyond those mentioned above. Your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 809. Conditions, if any, 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 (21 CFR Part 820) in the quality systems (QS) regulation (21 CFR Part 820).

U.S. Food & Drug Administration  
2025 New Hampshire Avenue  
Silver Spring, MD 20910  
301.495.7101



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and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1006.1050.

If you desire specific advice for your device on its labeling requirements (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-3041 or (301) 796-7100 or at its internet address <http://www.fda.gov/medicaldevices/resources/youindustry/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 Act (21 CFR Part 803), please go to <http://www.fda.gov/medicaldevices/safety/submitting-a-safety-report/default.htm> for the CDRE's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-3041 or (301) 796-7100 or at its internet address <http://www.fda.gov/oc/default.htm>.

Michael J. Ryan - S  
Dr. Eric Klein, M.D.,  
Acting Director  
Division of Anesthesiology,  
National Hospital of Neurology,  
Medicine, and Dental Devices  
Office of Device Evaluation,  
Center for Devices and Radiological Health

Enclosure



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
EPR - PMA Statement below

**Indications for Use**

510(k) Number (if any): K171873

Device Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs

Indications for Use (Describe):  
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy. Assessment of Medical Gloves for Penetration by Chemotherapy Drug

Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carbamide (BCNU) 1.0 mg/ml	14.7
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (CPA) 20 mg/ml	>240
Cytarabine (CT) 1 mg/ml	>240
Doxorubicin (DOX) 0.1 mg/ml	>240
Doxorubicin Hydrochloride 2.0 mg/ml	>240
Etoposide (Etopos) 20 mg/ml	>240
Fluorouracil (5FU) 500 mg/ml	>240
Irinotecan 10.0 mg/ml	>240
Methotrexate (MTX) 1 mg/ml	>240
Mitomycin (M) 0.1 mg/ml	>240
Mitomycin (M) 1 mg/ml	>240
Paclitaxel (Taxol) 0.1 mg/ml	>240
Thiopleg 10.0 mg/ml	56.8
Vincristine Sulfate 1.0 mg/ml	>240

Please note the following drugs had extremely low penetration times: Carbamide (BCNU) (1.0mg/ml) 14.7 minutes and Thiopleg (10 mg/ml) 56.8 minutes.

Type of Use (Select one or both, as applicable):  
 For Patient Use (Part 21 CFR Part Subpart D)  Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section is only to be completed by the PMA staff of 10/05.  
**"DO NOT SEND YOUR COMPLETED FORM TO THE PMA STAFF EMAIL ADDRESS BELOW."**  
 The burden lies for this collection of information is estimated to average 75 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:  
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 Office of Device Evaluation  
 Office of Product Regulation and Policy Staff  
 10855 NE 8th Ave  
 Seattle, WA 98125

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## REGULATION COMPLIANCE

### FDA 510K



### 510(k) SUMMARY K151750

**Preparation Date:** Nov. 8<sup>th</sup>, 2017

**Submitter:**

Company Name: Zhonghong Pulin Medical Products, Ltd.  
 Address: Puchang Industrial Park, Luchuan County, Tangshan, Hebei, 063502  
 Country: China  
 Phone No.: +86-315-4165740  
 Fax No.: +86-315-4167466  
 E-mail Address: [zhp@zhonghongpulin.com](mailto:zhp@zhonghongpulin.com)

**Contact Person:**

Contact Person: Li Qian (Regulatory Affairs Manager)  
 Contact Email: [liqian@zhonghongpulin.com](mailto:liqian@zhonghongpulin.com)

**Name of the Device:**

Device trade or proprietary name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs  
 Device common or usual name: Patient Examination Glove  
 Device Classification Name: LZA - Powder Free Patient Examination Glove  
 Device Classification Name: LZC - Patient Examination Glove Specialty  
 Regulation Number: LZA - 21 CFR 880.6250  
 FDA Device Class: Class I  
 Product Code: LZA, LZC

**Predicate Device:**

Class I patient Examination glove and tested for use with Chemotherapy Drugs, Powder Free, LZC, which meets all the requirements of ASTM D 6319-10 and FDA 21 CFR 880.6250.

Device Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs  
 Company Name: Kowon International Bhd.  
 510(K) Number: K151750





**Device Description:**

The subject device in this 510(k) Notification is a Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs

The subject device is a patient examination glove made from nitrile compound, blue in color, powder free and non-sterile (as per 21 CFR 880.6250, class I).

The principle operation of the medical device is to provide simple barrier protection for the wearer and the device meets all the requirements for Barrier Protection, tensile properties as defined in ASTM D6319-10 standard specifications for Nitrile Examination Gloves.

**Intended use of the Device (Indication of use)**

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

These gloves were tested for use with chemotherapy drugs per ASTM D6319-10 (Reapproved 2013) Standard Practice for Assessment of Medical Glove Penetration by Chemotherapy Drugs.

Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (BCNU) 130 mg/ml	14.7
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (Cytoxan) 50 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 100 mg/ml	>240
Doxorubicin Hydrochloride 2.0 mg/ml	>240
Etoposide (Toposar) 8.0 mg/ml	>240
Fluorouracil 50.0 mg/ml	>240
Ifosfamide 50.0 mg/ml	>240
Methotrexate 25 mg/ml	>240
Mitomycin C 0.5 mg/ml	>240
Mitoxantrone 2.0 mg/ml	>240
Paclitaxel (Taxol) 3.0 mg/ml	>240
Thiotepa 10.0 mg/ml	58.8
Vincristine Sulfate 1.0 mg/ml	>240

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU) 14.7 minutes and Thiotepa 58.8 minutes.





**Summary of the Technological Characteristics of the Device:**

The subject device is summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	Standard	Device performance
Dimension	ASTM standard D6319-10	Meets
Physical Properties	ASTM standard D6319-10	Meets
Freedom from pinholes	21 CFR 880.20 ASTM D6319-10	Meets
Powder Residual	ASTM D6319-10 and D6319-10 (Revised 2011)	Meets
Biocompatibility	ASTM D6319-10 Dermal sensitizer under the conditions of the study	Non-irritatory skin irritant under the conditions of the study No skin contact sensitizer under the conditions of the study

**Substantial Equivalence Based on Assessment of Non-Clinical Performance Data**

Bench tests were conducted to verify that the proposed device meets specifications and the proposed device is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:

ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical application.  
 ASTM D5151-06 (2011) Standard Test Method for Detection of Holes in Medical Gloves.  
 ASTM D6124-09 (2014) Standard Test Method for Residual Powder on Medical Gloves.  
 ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

The subject device meets the above test standards as stated by the test results. Both device has the same sizes, color, physical and dimensional characteristics.

The minimum breakthrough detection time of Carmustine for the subject device is below 30 minutes, similar with predicate K151750 (Blue).

The minimum breakthrough detection time of Thiotepa for the subject device is at 58.8 minutes. The subject device is having low permeation times than predicate K151750 (Blue).

Warning statement (Ds) associated with Carmustine and Thiotepa for subject device is included in Labeling, similar with the predicate device.

The subject device has similar thickness with predicate K151750 at palm, and similar length with predicate K151750 (Blue).





The subject device is having identical specification with predicate K151750 (Blue) with thickness at minimum 0.05mm and length at minimum 230mm.

The difference in labeling with additional drugs tested do not affect the safety and effectiveness of the subject device.

The subject device and the predicate device K151750 (Blue) share the same intended use, same nitrile material, same compliance with ASTM standard. There is no difference between the subject device and the predicate device K151750 (Blue) with respect to intended use, non-clinical performance data and technological characteristics.

Consequently, the gloves that are the subject of this submission are substantially equivalent to a legally marketed glove K151750 (Blue).

**Substantial Equivalence Based on Assessment of Clinical Performance Data**

Clinical data is not needed for this submission.

**Biocompatibility**

Biocompatibility tests indicate that under the conditions of the study, the gloves were non-sensitizing and non-irritating.

**Legally Marketed Device to which Substantial Equivalence is Claimed**

The legally marketed predicate device is specified as follows:

K151750 - Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile



## DECLARATION OF CONFORMITY

### Medical

**Zhonghong Pulin Medical Products Co.,Ltd.**  
Add: 35 Songhe Ave, Luannan County, Tangshan City, Hebei China, 063500  
 Tel: 0086-315-4167093 Fax: 0086-315-4168700

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**Declaration of Conformity**

Manufacturer: Zhonghong Pulin Medical Products Co.,Ltd.  
 Address: 35 Songhe Ave, Luannan County, Tangshan City, Hebei China, 063500  
 Tel: 86 315 4167093  
 Fax: 86 315 4168700

Product: Disposable Nitrile Examination Gloves  
 Designation: X-Small, Small, Medium, Large, X-Large, XX-Large

We herewith declare that the above-mentioned devices comply with the European Medical Device Regulation (EU) MDR 2017/745 and PPE Regulation (EU) 2016/425. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

By formulating the products, the chemical substances selecting was rigorous, and compliance to REACH, RoHS, Halogen-Free, SVHC 181.

We strict following the standard of U.S. and EU, no DEHP, BBP, DBP, and DIBP is using in any vinyl products.

**STANDARDS**

Standards Harmonized Standards applicable to this product are  
 EN455-1, EN455-2, EN455-3, EN455-4,  
 EN374-1, EN374-2, EN374-3, EN374-5.

Zhonghong Pulin Medical Products Co., Ltd.  
 中红普林医疗用品股份有限公司

Signature: \_\_\_\_\_  
 Date: March 02, 2021

### Medical

**Zhonghong Pulin Medical Products Co.,Ltd.**  
Add: West Industrial Park, Luannan County, Tangshan City, 063500, Hebei, China  
 Tel: 0086-315-4167093 Fax: 0086-315-4168700

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**EU Declaration of Conformity**

Manufacturer: Zhonghong Pulin Medical Products Co.,Ltd.  
 Address: West Industrial Park, Luannan County, Tangshan City, 063500 Hebei, China  
 SRN: CN-MF-000001106  
 European Lotus Nl, B.V  
 Representative: korzing, Julianaplein10, 1e Verd. 2595AA The Hague, Netherlands  
 SRN: NL-AR-000000121  
 Product: Disposable Medical nitrile exam glove  
 X-Small, Small, Medium, Large, X-Large  
 GAMN Code: 5608  
 UMON Code: 1182  
 Basic UDI: 6970426802-HPFN22XY

Classification (MDR, Annex VIII): Class I, Rule 1.  
 Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned de products ZHPFN02 meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer. Zhonghong Pulin Medical Products Co.,Ltd. is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:  
 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.  
 Applied standards, common specification, guidance:  
 EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009

Zhonghong Pulin Medical Products Co., Ltd.  
 中红普林医疗用品股份有限公司

Signature: \_\_\_\_\_  
 Date: July 06, 2021

### Chemical

**Zhonghong Pulin Medical Products Co.,Ltd.**  
Add: West Industrial Park, Luannan County, Tangshan City, 063500, Hebei, China  
 Tel: 0086-315-4167093 Fax: 0086-315-4168700

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**EU Declaration of Conformity - PPE**

The manufacturer:  
**Zhonghong Pulin Medical Products Co.,Ltd**  
 West Industrial Park, Luannan County,  
 Tangshan City, 063500, Hebei, China

Representative (EU, Switzerland): CURADEN AG, Amlehnstrasse 22, 6010 Kiens, Switzerland

Declares under his sole responsibility, that the PPE reference ZHPFN02 described hereafter:

Protective nitrile Glove  
 PPE to be used against Category III risks  
 EN ISO 374-3:2014 EN ISO 374-1:2014/Type B

is in conformity with the provisions of Regulation (EU)2016/425 and with the European harmonized standards EN ISO 374-1:2016+A1:2018/Type B, EN ISO 374-5:2016, EN ISO 21420:2020 and is identical to the PPE which is subject to the EU-Type examination, under certificate number 2777, issued by the Notified Body:  
 SATRA Technology Europe Limited  
 Bracebrook Business Park, Clonsilla  
 D15YNQ9, Republic of Ireland

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified body:  
 SATRA Technology Europe Limited  
 Bracebrook Business Park, Clonsilla  
 D15YNQ9, Republic of Ireland

Zhonghong Pulin Medical Products Co., Ltd.  
 中红普林医疗用品股份有限公司

Signature: \_\_\_\_\_  
 Date: January 04, 2022





**curaGRIP – A SWISS BRAND**  
by CURADEN  
**Headquarter: CURADEN AG**  
Arملهnerstraße 22  
CH-6010 Kriens, Europe

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