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CERTIFICATIONS

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INDEX:



MANUFACTURING ACCREDITATIONS

ISO 9001: 2015

CQC

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 00121Q30150R3M/1300

We hereby certify that

Zhonghong Pulin Medical Products Co.,Ltd.

Registered Address: West Industrial Park, Luannan County, Tangshan City, Hebei Province, P.R.China
Production address: Pachigang Industrial Park, Luannan County, Tangshan City, Hebei Province, P.R.China (Nitrile);
South of Ningtuo Village, Pachigang Town, Luannan County, Tangshan City, Hebei Province, P.R.China (Vinyl);
North of Liangtuo Village, Pachigang Town, Luannan County, Tangshan City, Hebei Province, P.R.China (Vinyl);
South of Paituo Village, Sigezhuang Town, Luannan County, Tangshan City, Hebei Province, P.R.China (Vinyl);
West Industrial Park, Luannan County, Tangshan City, Hebei Province, P.R.China (Nitrile)

by reason of its
Quality Management System
has been awarded this certificate for compliance with the standard

GB/T 19001-2016 / ISO 9001:2015

The Quality Management System Applies in the following area:

Design, Development and Production of Nitrile and Vinyl Gloves

Certified since: January 17, 2012 Valid from: January 5, 2021 Valid until: January 7, 2024

IAF CNAS IQNet

CHINA QUALITY CERTIFICATION CENTRE

A 0101359

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 Deutsche Akkreditierungsstelle


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

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

DAkkS Deutsche Akkreditierungsstelle


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. Pachigang 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 Peituozi Village, Sigezhuang 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
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle


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

Date: April 13, 2021

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,

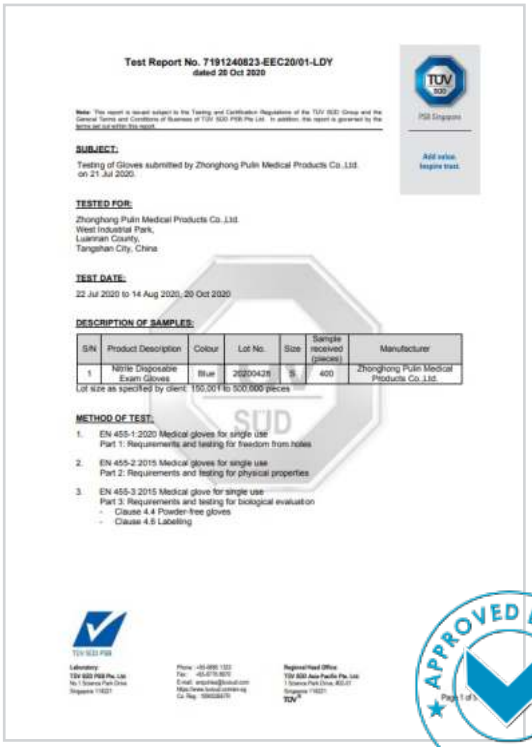
Jing Zhang
Certification body

TÜV Rheinland LGA Products GmbH
Am Grauen Stein
51105 Köln
Germany

Headquarter
Tillystraße 2
90431 Nürnberg

INTERNATIONAL STANDARDS

EN 455:1-4



Test Report No. 7191240823-EEC20/01-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,
Luannan County,
Tangshan City, China

TEST DATE:

22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

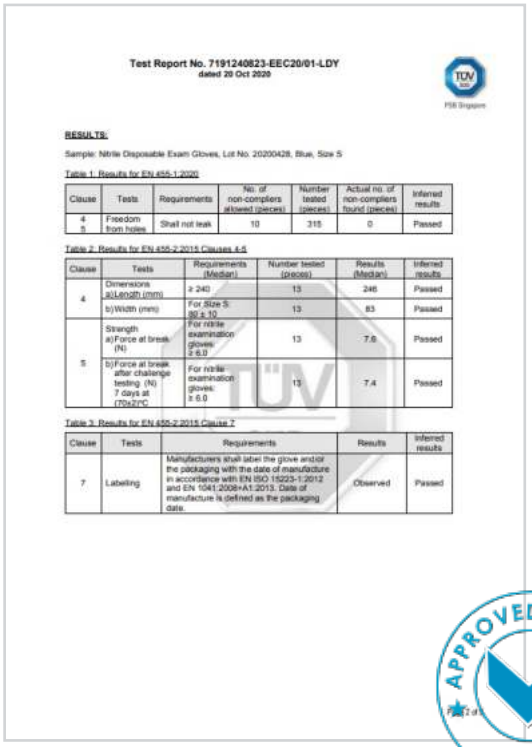
DESCRIPTION OF SAMPLES:

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

Lot size as specified by client: 150,001 to 500,000 pieces

METHOD OF TEST:

1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes
2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties
3. 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



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

RESULTS:

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

Table 1: Results for EN 455-1:2020

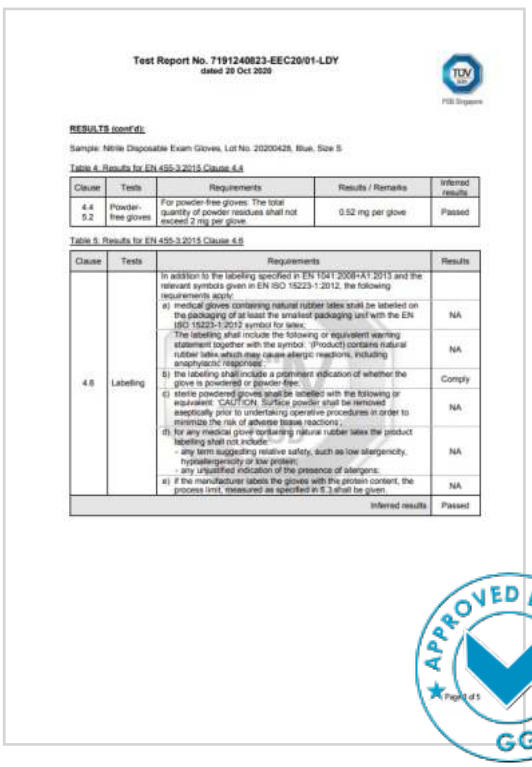
Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	0	Passed

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

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	≥ 240	13	246	Passed
	b) Width (mm)	For Size S: 80 ± 10	13	83	Passed
5	Strength a) Force at break (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 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+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. 20200428, Blue, Size S

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

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4 5.2	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	Labelling	In addition to the labelling specified in EN 1041:2008+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 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 responses.'	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		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:	NA
		- any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein;	
		- any unjustified indication of the presence of allergens;	
		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-EEC20/01-LDY
dated 20 Oct 2020

REMARKS:

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

Yeo Poh Kwang
Associate Engineer

Lee Chi 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

INTERNATIONAL STANDARDS

EN 455:1-4

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

TÜV SÜD PSB Singapore

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

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2. The samples mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
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Effective 01 September 2020

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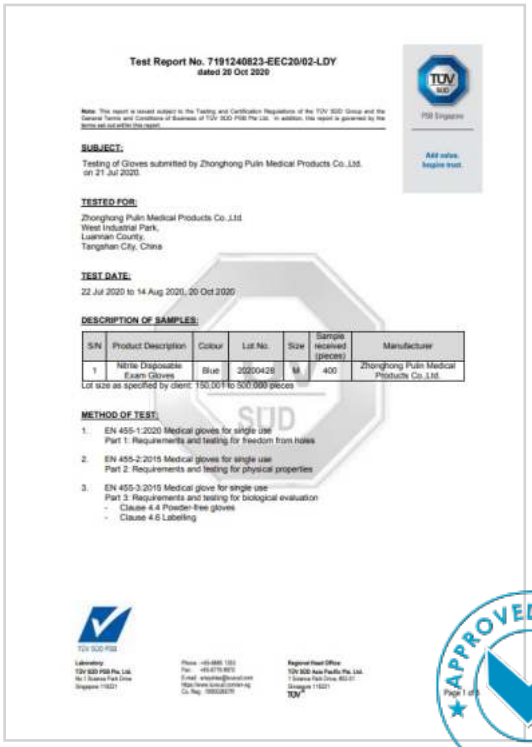

Test Report No. 7191240823-EEC20/02-LDY
dated 20 Oct 2020

TÜV SÜD PSB Singapore

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Add value. Inspire trust.

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,
Luannan 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	M	400	Zhonghong Pulin Medical Products Co.,Ltd.

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

METHOD OF TEST:

1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes
2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties
3. 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

TÜV SÜD PSB

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

Phone: +65 6885 1333
Fax: +65 6779 5972
E-mail: enquiries@tuvsud.com
https://www.tuvsud.com/en-sg
Co. Reg.: 199002667R

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

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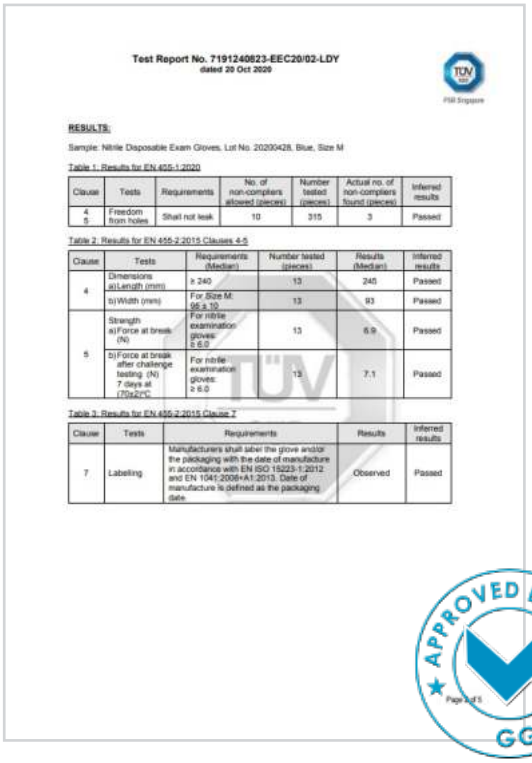

Test Report No. 7191240823-EEC20/02-LDY
dated 20 Oct 2020

TÜV SÜD PSB Singapore

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 5	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	Dimensions a) Length (mm)	≥ 240	13	245	Passed
	b) Width (mm)	For Size M: 95 ± 10	13	93	Passed
5	Strength 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 (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	7.1	Passed

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

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

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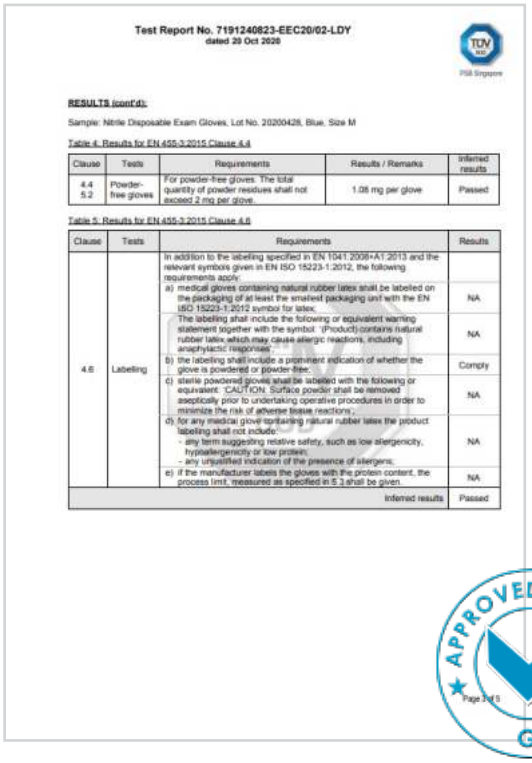

Test Report No. 7191240823-EEC20/02-LDY
dated 20 Oct 2020

TÜV SÜD PSB Singapore

RESULTS (cont'd):

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

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

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4 5.2	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 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+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 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 responses";	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		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:	
		- any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein;	NA
		- any unjustified indication of the presence of allergens;	
		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

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INTERNATIONAL STANDARDS

EN 455:1-4

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

TÜV SÜD PSB Singapore

REMARKS:

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

Yeo Poh Kwang
Associate Engineer

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

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APPROVED BY GGL

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

TÜV SÜD PSB Singapore

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

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6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 01 September 2020

TÜV SÜD

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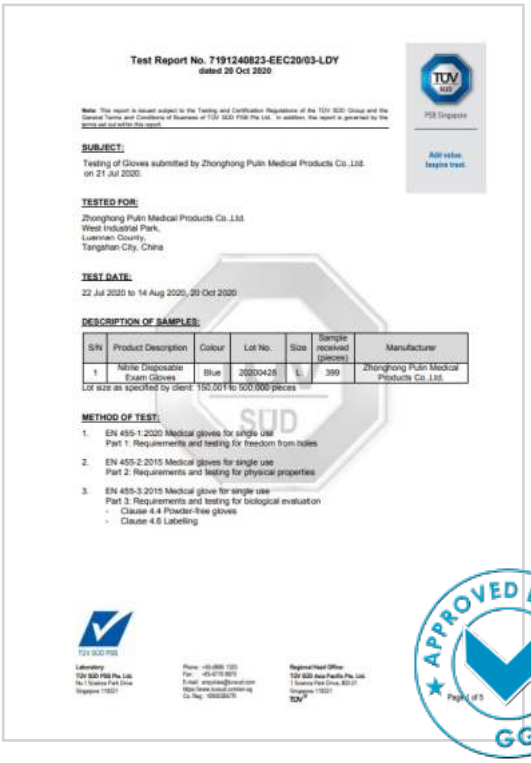

Test Report No. 7191240823-EEC20/03-LDY
dated 20 Oct 2020

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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,
Luannan 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	L	399	Zhonghong Pulin Medical Products Co.,Ltd.

Lot size as specified by client: 150,001 to 500,000 pieces

METHOD OF TEST:

1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes
2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties
3. 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

TÜV SÜD PSB

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

Phone: +65-6885 1333
Fax: +65-6778 8670
E-mail: enquiries@tuvsud.com
Web:www.tuvsud.com/en-sg
Co. Reg.: 199002667R

Regional Head Office
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #03-01
Singapore 118221

TÜV

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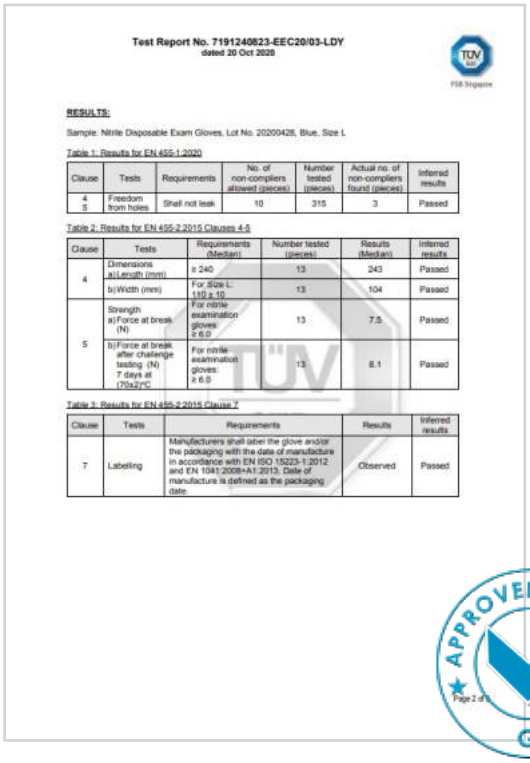

Test Report No. 7191240823-EEC20/03-LDY
dated 20 Oct 2020

TÜV SÜD PSB Singapore

RESULTS:

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

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 5	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	Dimensions a) Length (mm)	≥ 240	13	243	Passed
	b) Width (mm)	For Size L: 110 ± 10	13	104	Passed
5	Strength 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 (70±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	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

Page 2 of 5

APPROVED BY GGL

INTERNATIONAL STANDARDS

EN 455:1-4

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

TÜV SÜD PSB Singapore

RESULTS (cont'd):

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

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

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4 5.2	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 1041:2008+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 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 responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		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:	
		- any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein;	NA
		- any unqualified indication of the presence of allergens;	
		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

TÜV SÜD PSB Singapore

REMARKS:

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

Yeo Poh Kwang
Associate Engineer

Lee Lai 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

TÜV SÜD PSB Singapore

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5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.
6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 01 September 2020

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

TÜV SÜD PSB Singapore

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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,
Luannan 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: 150,001 to 500,000 pieces

METHOD OF TEST:

1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes
2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties
3. 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

TÜV SÜD PSB

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

Phone: +65 6885 1333
Fax: +65 6775 5870
E-mail: enquiries@tuvsud.com
https://www.tuvsud.com/en-sg
Co. Reg.: 199002947K

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

INTERNATIONAL STANDARDS

EN 455:1-4

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

TÜV SÜD PSB Singapore

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 5	Freedom from holes	Shall not leak	10	315	2	Passed

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

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions: a)Length (mm)	≥ 240	13	249	Passed
	b)Width (mm)	For Size XL: ≥ 110	13	114	Passed
5	Strength 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 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

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

TÜV SÜD PSB Singapore

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 5.2	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	Labelling	In addition to the labelling specified in EN 1041:2008+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 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 responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		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: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 6.3,shall be given.	NA
			Inferred results: Passed

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

TÜV SÜD PSB Singapore

REMARKS:

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

Yeo Poh Kwang
Associate Engineer

Lee Lay 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-EEC20/04-LDY
dated 20 Oct 2020

TÜV SÜD PSB Singapore

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Effective 01 September 2020

INTERNATIONAL STANDARDS

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

SATRA TECHNOLOGY

SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden, Xiping
Nancheng District, Dongguan City
Guangdong Province, China
Tel: +86 (0) 769 22888020
email: info@satrafe.com

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

SATRA reference: CHT0309328 /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(5-6), S(6-7), M(7-8), L(8-9), XL(9-10).

Conditions of Issue:

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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 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.

The uncertainty of the results (UoM) 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)

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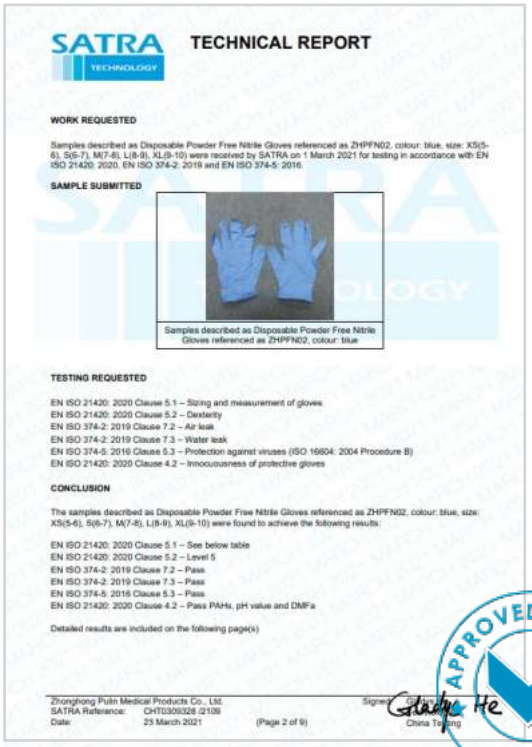

SATRA TECHNOLOGY

TECHNICAL REPORT

WORK REQUESTED

Samples described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: blue, size: XS(5-6), 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(5-6), 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 DMFa

Detailed results are included on the following page(s)

Zhonghong Pulin Medical Products Co., Ltd.
SATRA Reference: CHT0309328 /2109
Date: 23 March 2021

Signed: Gladys He, China Testing

(Page 2 of 9)

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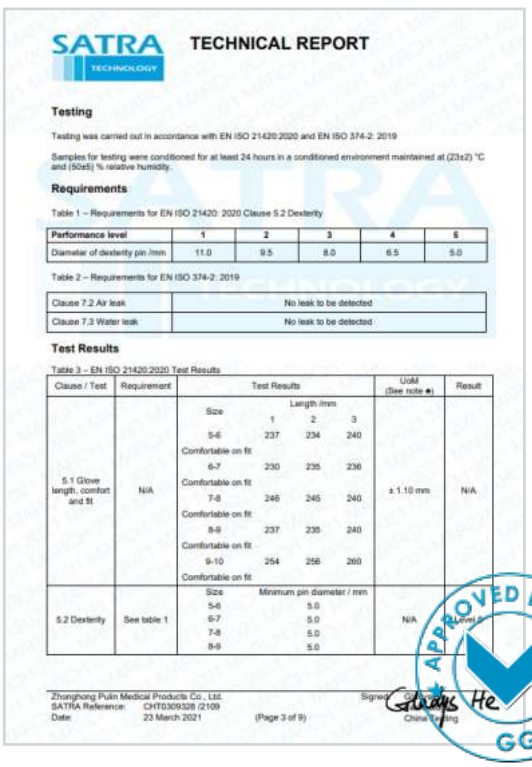

SATRA TECHNOLOGY

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				UoM (See note ◆)	Result
5.1 Glove length, comfort and fit	N/A	Size	Length /mm 1	2	3	±1.10 mm	N/A
		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	256	260		
		Comfortable on fit					
5.2 Dexterity	See table 1	Size	Minimum pin diameter / mm			N/A	Level 5
		5-6	5.0				
		6-7	5.0				
		7-8	5.0				
		8-9	5.0				

Zhonghong Pulin Medical Products Co., Ltd.
SATRA Reference: CHT0309328 /2109
Date: 23 March 2021

Signed: Gladys He, China Testing

(Page 3 of 9)

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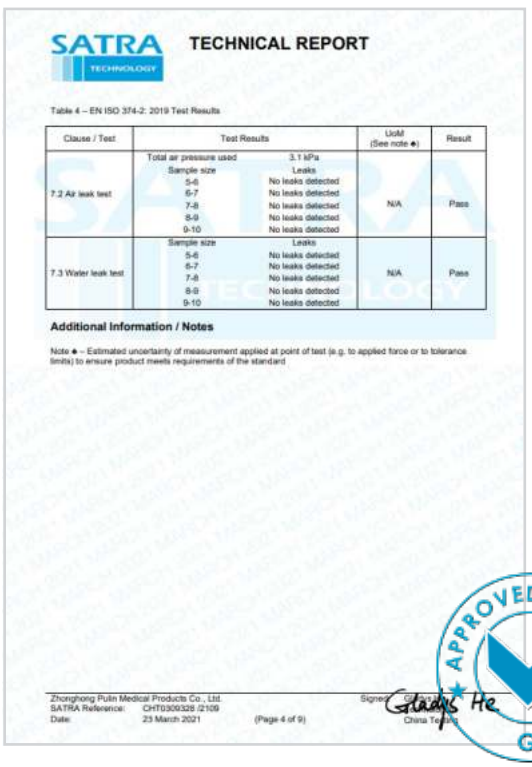

SATRA TECHNOLOGY

TECHNICAL REPORT

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

Clause / Test	Test Results		UoM (See note ◆)	Result
7.2 Air leak test	Total air pressure used	3.1 kPa	N/A	Pass
	Sample size	Leaks		
	5-6	No leaks detected		
	6-7	No leaks detected		
	7-8	No leaks detected		
	8-9	No leaks detected		
	9-10	No leaks detected		
7.3 Water leak test	Sample size	Leaks	N/A	Pass
	5-6	No leaks detected		
	6-7	No leaks detected		
	7-8	No leaks detected		
	8-9	No leaks detected		
	9-10	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

Zhonghong Pulin Medical Products Co., Ltd.
SATRA Reference: CHT0309328 /2109
Date: 23 March 2021

Signed: Gladys He, China Testing

(Page 4 of 9)

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INTERNATIONAL STANDARDS

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

SATRA TECHNOLOGY

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 16604: 2004 included in their accreditation schedule.

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

Sample description: Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: blue

Test method	Specimen	Step 1 (0 kPa, 5 min)	Step 2 (14 kPa, 1min)	Step 3 (0kPa, 4min)	Titre of phage Phi-X174 (PFU /mL)	Comment
ISO 16604: 2004 Procedure B Using retaining screen	+ control	Penetration	Penetration	Penetration	Penetration	Acceptable
	- control	No penetration	No penetration	No penetration	< 1	Acceptable
	1	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	2	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	3	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass

Zhonghong Pulin Medical Products Co., Ltd.
SATRA Reference: CHT0309328 /2109
Date: 23 March 2021 (Page 5 of 9)

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SATRA TECHNOLOGY

TECHNICAL REPORT

Innocuousness Test Results

Testing was conducted at a third-party laboratory and reported under their reference A210304071001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
I001	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue	Gloves	-

pH Value - EN ISO 21420:2020

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

Requirement:	3.5-9.5

-	Unit	Result
Test Item(s)	-	I001
Test Method	-	II
Parameter	-	-
pH Value of Extracting Solution	-	5.46
Temp. of Aqueous Extract	deg. C	25.1
pH Value of Aqueous Extract	-	7.4
Difference Figure	-	-
Conclusion	-	PASS

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

Zhonghong Pulin Medical Products Co., Ltd.
SATRA Reference: CHT0309328 /2109
Date: 23 March 2021 (Page 6 of 9)

Signed: Gladys He, China Testing

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SATRA TECHNOLOGY

TECHNICAL REPORT

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

Test Method : With reference to test method PD CEN ISO/TS 16190:2013.

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

Tested Item(s)	Result			Conclusion
	Detected Analyte(s)	Conc.	Unit	
I001	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

List of Polynuclear Aromatic Hydrocarbons:

No.	Name of Analytes	CAS-No.	No.	Name of Analytes	CAS-No.
1	Chrysene	218-01-9	5	Dibenzo (a,h) anthracene	53-70-3
2	Benzo (a) pyrene	50-32-8	6	Benzo (b) fluoranthene	205-99-2
3	Benzo (e) pyrene	192-97-2	7	Benzo (j) fluoranthene	205-82-3
4	Benzo (a) anthracene	56-55-3	8	Benzo (k) fluoranthene	207-08-9

Dimethylformamide(DMFA) Content - EN ISO 21420:2020

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

Analyte	Unit	Result	Client's Requirement
		Test Item(s)	
		I001	
Dimethylformamide(DMFA)	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 ***

Zhonghong Pulin Medical Products Co., Ltd.
SATRA Reference: CHT0309328 /2109
Date: 23 March 2021 (Page 7 of 9)

Signed: Gladys He, China Testing

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SATRA TECHNOLOGY

TECHNICAL REPORT

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

1. GENERAL
2. SUSPENSION OR TERMINATION OF SERVICES
3. PAYMENT
4. MISCELLANEOUS
5. DISCLAIMER AND LIMITATION OF LIABILITY
6. INDEMNITY
7. CONFIDENTIALITY
8. INTELLECTUAL PROPERTY RIGHTS
9. DISPUTE RESOLUTION
10. GOVERNING LAW AND JURISDICTION

Zhonghong Pulin Medical Products Co., Ltd.
SATRA Reference: CHT0309328 /2109
Date: 23 March 2021 (Page 8 of 9)

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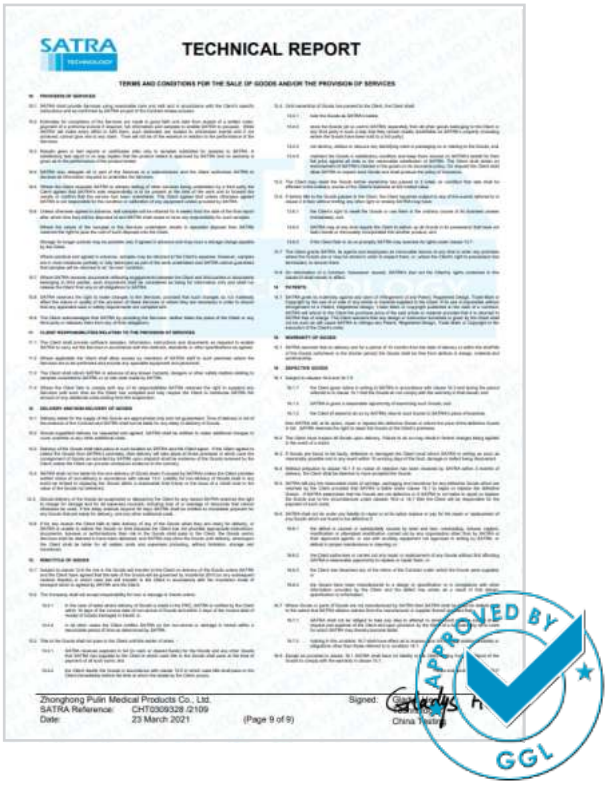
INTERNATIONAL STANDARDS

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



SATRA TECHNOLOGY

TECHNICAL REPORT

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

Zhonghong Pulin Medical Products Co., Ltd.
SATRA Reference: CHT0309328 /2109
Date: 23 March 2021

(Page 9 of 9)

Signed:
China Testing

APPROVED BY GGL

INTERNATIONAL STANDARDS

EN 374-1, EN 16523

SATRA Technology Centre Ltd
Wyndham Way, Telford Way, Kettering,
Northamptonshire, NN16 8SD United Kingdom
Tel: +44 (0) 1536 410000
Fax +44 (0) 1536 410626
email: info@satra.com
www.satra.com

Customer details: SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden
Hongwei Road
Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079

SATRA reference: CHM03141555/2122/LC
Your reference: CHT03133568
Date of report: 15th July 2021
Samples received: 1st June 2021
Date(s) work carried out: 3rd June to 8th July 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer:Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan 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:

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Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked # fall outside the UKAS Accreditation Schedule for SATRA.

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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-binary acceptance which itself is based on the guard band being equal to the expanded 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: Technologist
Department: Chemical & Analytical Technology

(Page 1 of 10)

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SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM03141555/2122/LC
Date: 15th July 2021

(Page 2 of 10)

Signed:

TECHNICAL REPORT

WORK REQUESTED:

Samples of gloves described as ZHPFN02, colour: Blue were received on the 1st 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: 142-82-5)	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: CHM03141555/2122/LC
Date: 15th July 2021

(Page 3 of 10)

Signed:

TECHNICAL REPORT

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: CHM03141555/2122/LC
Date: 15th July 2021

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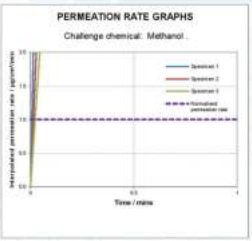
Signed:

TECHNICAL REPORT

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/cm²/min	
		Detection technique:	GC-FID (periodic measurement)	
		Collection medium:	Dry air (open loop)	
		Collection medium flow rate:	335 – 380 ml/min	
		Test temperature:	(23 ± 1) °C	
Using stainless steel permeation cells with standardised dimensions	Specimen	Thickness (mm):	Breakthrough time (mins)*	
	1	0.08	<1	
	2	0.08	<1	
	3	0.08	<1	
		Test result:	<1	
		UoM:	<1	
Visual appearance of specimens after testing:		Swollen		

PERMEATION RATE GRAPHS

Challenge chemical: Methanol



SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM03141555/2122/LC
Date: 15th July 2021

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Signed:

INTERNATIONAL STANDARDS

EN 374-1, EN 16523

SATRA TECHNOLOGY

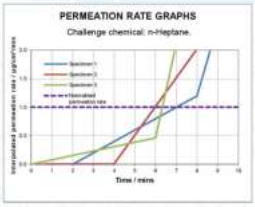
TECHNICAL REPORT

UKAS 0248

Test/Property	Sample reference:	ZHPFN02, colour: Blue		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-006	Test information:	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/cm²/min	
		Detection technique:	GC-FID (periodic measurement)	
		Collection medium:	Dry air (open loop)	
		Collection medium flow rate:	335 – 380 ml/min	
		Test temperature:	(23 ± 1) °C	
Using stainless steel permeation cells with standardised dimensions	Specimen	Thickness (mm)◇	Breakthrough time (mins)*	
	1	0.07	7	
	2	0.07	5	
	3	0.07	6	
		Test result:	5	
		UoM:	<1	
Visual appearance of specimens after testing:		Swollen		

PERMEATION RATE GRAPHS

Challenge chemical: n-Heptane



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SATRA TECHNOLOGY

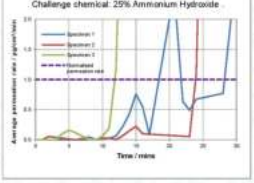
TECHNICAL REPORT

UKAS 0248

Test/Property	Sample reference:	ZHPFN02, colour: Blue		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009	Test information:	Chemical:	25% Ammonium hydroxide	Level 1
		Normalised permeation rate (NPR):	1 µg/cm²/min	
		Detection technique:	Conductimetry (continuous measurement)	
		Collection medium:	Deionised water (closed loop)	
		Collection medium stirring rate: (each cell constant to within ± 10%)	45 – 65 ml/min	
		Test temperature:	(23 ± 1) °C	
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)◇	Breakthrough time (mins)	
	1	0.08	19	
	2	0.08	24	
	3	0.08	12	
		Test result:	12	
		UoM:	<1	
Visual appearance of specimens after testing:		Swollen and discoloured		

PERMEATION RATE GRAPHS

Challenge chemical: 25% Ammonium Hydroxide



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SATRA TECHNOLOGY

TECHNICAL REPORT

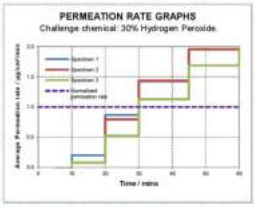
UKAS 0248

Test/Property	Sample reference:	ZHPFN02, colour: Blue		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025	Test information:	Chemical:	30% Hydrogen peroxide	Level 2
		Normalised permeation rate (NPR):	1 µg/cm²/min	
		Detection technique:	Electrochemical detector (periodic measurement)	
		Collection medium:	Deionised water (closed loop)	
		Collection medium stirring rate: (each cell constant to within ± 10%)	45 – 65 ml/min	
		Test temperature:	(23 ± 1) °C	
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)◇	Breakthrough time (mins)*	
	1	0.07	Between 31 to 45	
	2	0.08	Between 31 to 45	
	3	0.08	Between 31 to 45	
		Test result:	Between 31 to 45	
		UoM:	See below	
Visual appearance of specimens after testing:		Swollen and slighty discoloured		

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.

PERMEATION RATE GRAPHS

Challenge chemical: 30% Hydrogen Peroxide.



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

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SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS 0248

◇ 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.

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INTERNATIONAL STANDARDS

EN 374-4

SATRA TECHNOLOGY

SATRA Technology Centre Ltd
Wyndham Way, Telford Way, Kettering,
Northamptonshire, NN16 8SD United Kingdom
Tel: +44 (0) 1536 410000
Fax +44 (0) 1536 410626
email: info@satra.com
www.satra.com

UKAS TESTING 0248

Customer details: SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden
Hongwei Road
Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079

SATRA reference: CHM0309851/2110/LC
Your reference: CHT0309328
Date of report: 28th April 2021
Samples received: 5th March 2021
Date(s) work carried out: 16th to 24th April 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer:Zhonghong Pulin 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. Comments 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 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) 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 corrected for uncertainty on a worst-case basis falls outside of the requirement or specification then the risk of a pass result being a false accept is up to 50%. We will therefore not provide either a pass or fail statement 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 Cove
Position: Technologist
Department: Chemical & Analytical Technology

(Page 1 of 6)

SATRA Technology Centre Ltd (a subsidiary of SATRA). Registered in England No. 3858296 at the above address

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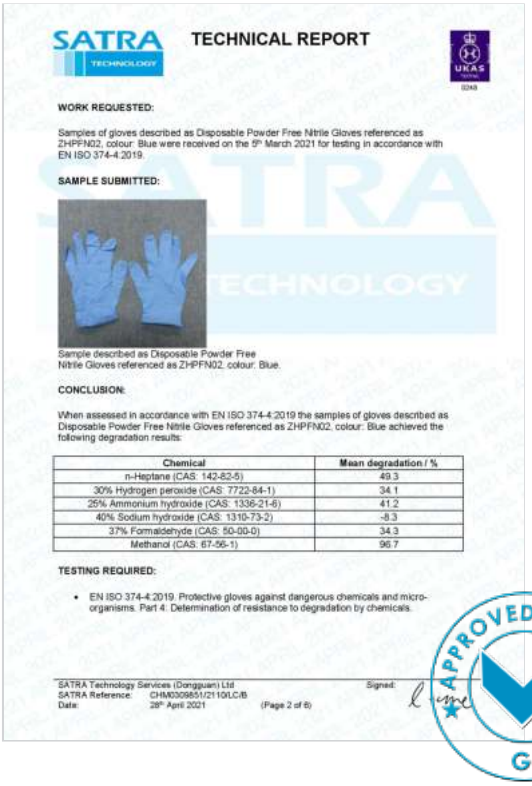

SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

WORK REQUESTED:

Samples of gloves described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue were received on the 5th 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: 142-82-5)	49.3
30% Hydrogen peroxide (CAS: 7722-84-1)	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: CHM0309851/2110/LC/B
Date: 28th April 2021
Signed:
(Page 2 of 6)

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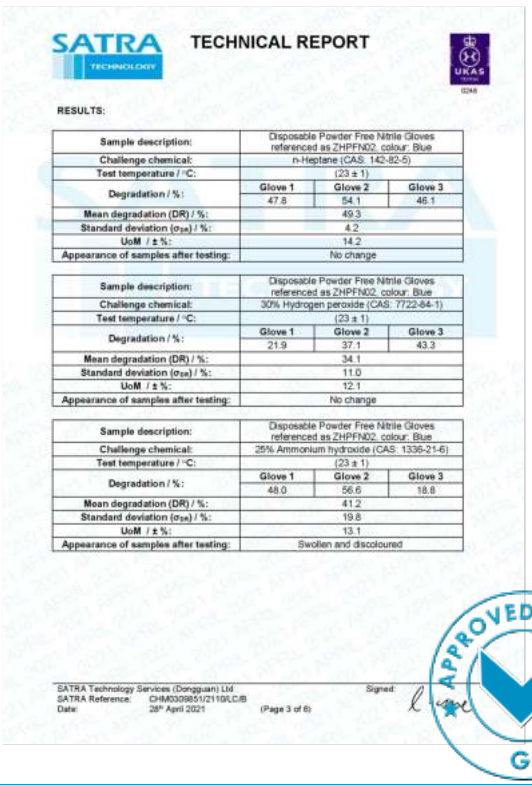


SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

RESULTS:

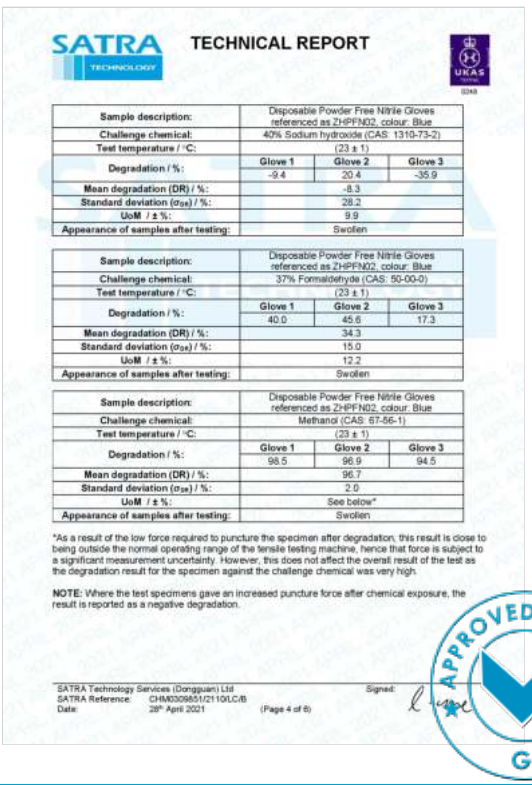
Sample description:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
Challenge chemical:	n-Heptane (CAS: 142-82-5)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	47.8	54.1	46.1
Mean degradation (DR) / %:	49.3		
Standard deviation (σ_{DR}) / %:	4.2		
UoM / ± %:	14.2		
Appearance of samples after testing:	No change		

Sample description:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	21.9	37.1	43.3
Mean degradation (DR) / %:	34.1		
Standard deviation (σ_{DR}) / %:	11.0		
UoM / ± %:	12.1		
Appearance of samples after testing:	No change		

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

SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM0309851/2110/LC/B
Date: 28th April 2021
Signed:
(Page 3 of 6)

APPROVED BY GGL



SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

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

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

Sample description:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
Challenge chemical:	Methanol (CAS: 67-56-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	98.5	96.9	94.5
Mean degradation (DR) / %:	96.7		
Standard deviation (σ_{DR}) / %:	2.0		
UoM / ± %:	See below*		
Appearance of samples after testing:	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: CHM0309851/2110/LC/B
Date: 28th April 2021
Signed:
(Page 4 of 6)

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REGULATION COMPLIANCE

CE 2777

Issued to:

SATRA TECHNOLOGY

Notified Body: 2777 SATRA customer number:

EU Type-Examination Certificate

Certificate number:

This 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 III product.

Product reference: **Description:**

Disposable Powder Free Nitrile Gloves.
Colour: Blue, Black

Sizes:
XS(5-6)
S(6-7)
M(7-8)
L(8-9)
XL(9-10)

Classification:

EN ISO 374-1:2016+A1:2018/Type B	Level	EN ISO 374-4:2019 Degradation %
(K) Sodium hydroxide 40%	6	-8.3
(P) Hydrogen peroxide 30%	2	34.1
(T) Formaldehyde 37%	4	34.3

EN ISO 374-5:2016	Level
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: Quincey Brown

Date first issued: 26/08/2021
Date of issue: 26/08/2021
Expiry date: 25/08/2026

Page 1 of 2

SATRA Technology Europe Limited, Bradshaw Business Park, Clonee, D15Y5CP, Republic of Ireland

APPROVED BY GGL

INTERNATIONAL STANDARDS

EN 1186

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

SUBJECT	Chemical Test
TEST LOCATION	TÜV SÜD China TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	Zhonghong Pulin Medical Products Co., Ltd.
CLIENT ADDRESS	West Industrial Park, Luannan 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)
Report Drafter

Authorized By
(Leo Li)
Authorized Signatory

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 CLIENTS 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 Europe Resolution Res AP (2004) 4 on rubber to be used for food contact applications.
   - As specified in REGULATION (EU) No 10/2011 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

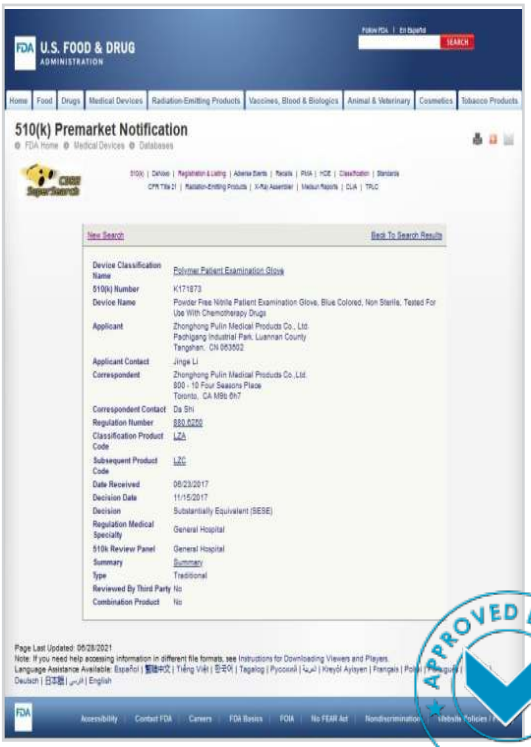
Simulant(s) Used	Test Condition	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
10% Ethanol	70 °C for 2 hours	<5.0	60
3% Acetic acid	70 °C for 2 hours	<5.0	60
95% Ethanol	60 °C for 2 hours	<5.0	60
Iso-octane	40 °C for 0.5 hour	<5.0	60

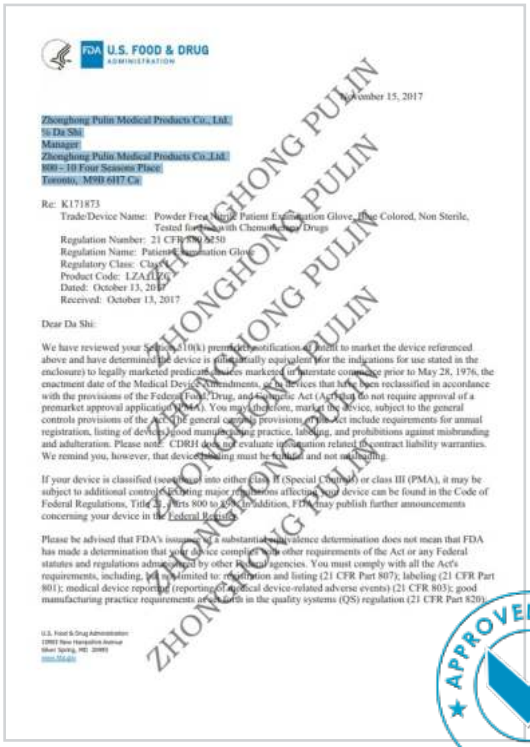
Note: 1. mg/kg denotes milligram per kilogram foodstuff
2. Specification is quoted from European Resolution Res AP (2004) 4 on rubber to be used for food contact applications
3. < denotes less than
Note: This report is for internal use only by the client.

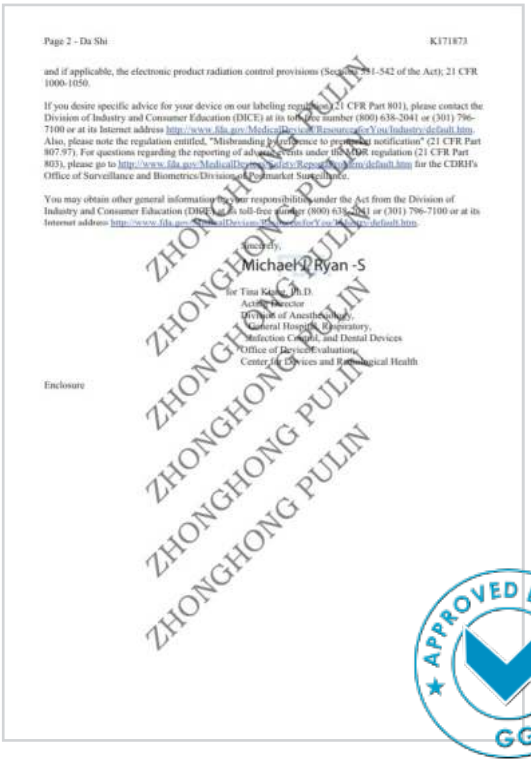
-END OF THE TEST REPORT-

REGULATION COMPLIANCE

FDA 510K







REGULATION COMPLIANCE

FDA 510K

ZHONG HONG PULIN

510(k) SUMMARY K171873

Preparation Date: Nov. 8th, 2017

Submitter:

Company Name: Zhonghong Pulin Medical Products Co., Ltd.
Address: Pachigang Industrial Park, Jinnan District, Tangshan, Hebei, 063502
Country: China
Phone No.: 86-315-4165760
Fax No.: 86-315- 4167665
E-mail Address: RA@zhonghongpulin.com

Contact Person:

Contact Person : Li Jiang (Regulatory Affairs Manager)
Contact Email: RA@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 - Polymer Patient Examination Glove
Device Classification Name: LZC - Patient Examination Glove Specialty
Regulation Number: 21 CFR 880.6250
FDA Device Class: Class 1
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 requirement 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
Copmany Name: Kossan International Sdn. Bhd.
510(K) Number: K151750

1 of 4

ZHONG HONG PULIN

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).

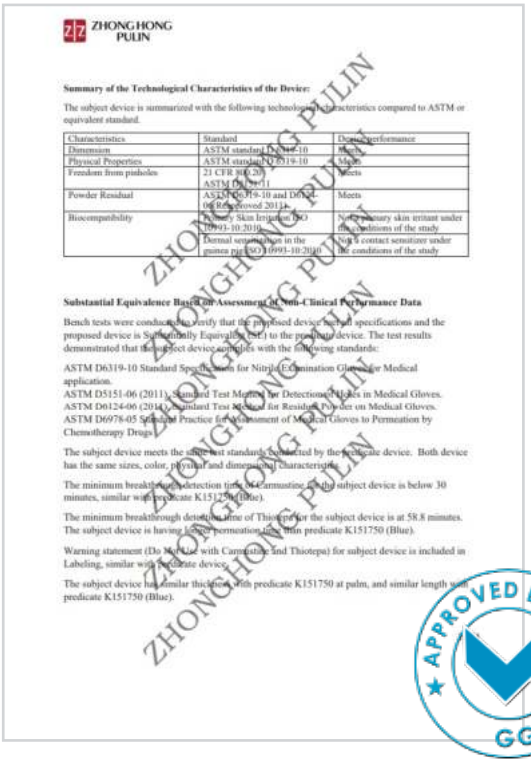
The principle operation of the medical device is to provide single use barrier protection for the wearer and the device meets all the requirement specifications for Barrier Protection, tensile properties as defined in ASTM D6319-10 Standard specification for Nitrile Examination Gloves.

Intended use of the Device (Indication for 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 D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (BCNU) 3.3 mg/ml	14.7
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (Cytoxan) 20 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 100 mg/ml	>240
Doxorubicin Hydrochloride 2.0 mg/ml	>240
Etoposide (Toposar) 20 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) 6.0 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.



ZHONG HONG PULIN

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 D 6319-10	Meets
Freedom from pinholes	21 CFR 800.20 / ASTM D5151-11	Meets
Powder Residual	ASTM D6319-10 and D6124-06 (Reapproved 2013)	Meets
Biocompatibility	Primary Skin Irritation ISO 10993-10:2010	Non-Primary skin irritant under the conditions of the study
	Dermal sensitization in the guinea pig ISO 10993-10:2010	Non-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 has all 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 D6124-06 (2011) Standard Test Method for Residual Powder on Medical Gloves.
ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

The subject device meets the same test standards conducted by the predicate device. Both device has the same sizes, color, physical and dimensional characteristics.

The minimum breakthrough detection time (BT) 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 longer permeation time than predicate K151750 (Blue).

Warning statement (Do Not Use with Carmustine and Thiotepa) for subject device is included in Labeling, similar with predicate device.

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

ZHONG HONG PULIN

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 Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not needed for this submission.

Biocompatibility

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

Legally Marketed Device to which Substantial Equivalence is Claimed

The legally marketed predicate device in scope is as follows:

K151750 - Powder Free Nitrile Patient Examination Glove, White 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:0086-315-4167693 Fax:0086-315-4168700

Declaration of Conformity

Manufacturer: Zhonghong Pulin Medical Products Co.,Ltd.
Address: 35 Songhe Ave, Luannan County, Tangshan City, Hebei China. 063500
Tel: 86 315 4167693
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.

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

Signature:

Date: March 02, 2021

Medical

Zhonghong Pulin Medical Products Co.,Ltd.

Add: West Industrial Park, Luannan County, Tangshan City, 063500, Hebei, China
Tel:0086-315-4167693 Fax:0086-315-4168700

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-000001108
European	Lotus NL B.V
Representative:	koningin Julianaplein10, 1e Verd, 2595AA The Hague, Netherlands
SRN:	NL-AR-000000121
Product:	Disposable Medical nitrile exam glove X-Small, Small, Medium, Large, X-Large
GMDN Code:	56286
UMDN Code:	11882
Basic UDI:	697040580ZHPFN02XY

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

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

Signature:

Date: July 06, 2021

Chemical

Zhonghong Pulin Medical Products Co.,Ltd.

Add: West Industrial Park, Luannan County, Tangshan City, 063500, Hebei, China
Tel:0086-315-4167693 Fax:0086-315-4168700

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 Kriens, 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 374-5:2016 EN ISO 374-1:2016/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
Bracetown Business Park, Clonee
D15YN2P, 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
Bracetown Business Park, Clonee
D15YN2P, Republic of Ireland

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

Date: January 04, 2022

PACKAGING


VELVET GRIP
NITRILE Examination GLOVES
curaden
• Disposable Gloves
• Non-sterile
• Ambidextrous
• Powder-free and blue
• Latex-free
100 GLOVES
Size L
VELVET GRIP
Einweg NITRIL-HANDSCHUHE
curaden
• Untersuchungshandschuhe
• Nicht steril
• Beidseitig
• Puderfrei und blau
• Latexfrei
100 HAND SCHUHE
Größe L
VELVET GRIP
NITRILE Examination GLOVES
Importer and Distributor:
CURADEN AG
Amlehnstrasse 22,
CH-6010 Kriens, gloves@curaden.ch
LOTUS NL B.V., Koningin Julianaplein 10,
1e Verd. 2595AA The Hague, Netherlands
Tel.: +31644160999
4 260740 980185
REF ZHPFN02
MADE IN PRC
VELVET GRIP
GUANTI IN NITRILE monouso
curaden
100 GUANTI
Dimensione L
VELVET GRIP
GUANTES DE NITRILO desechables
curaden
100 GUANTES
Talla L
VELVET GRIP
GANTS NITRILE jetables
curaden
100 GANTS
Taille L

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

Locations: Austria, Benelux, Denmark, France, Germany, Italy, Poland, Slovakia, Slovenia, United Kingdom, Brazil, Mexico, USA, Australia, India, Japan, Singapre, South Korea, Thailandi

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