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

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

Digitally signed by Guțan Ghenadie
Date: 2021.09.11 10:59:35 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

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: - 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 5.3 shall be given.	NA
		Inferred results	Passed

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 Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

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

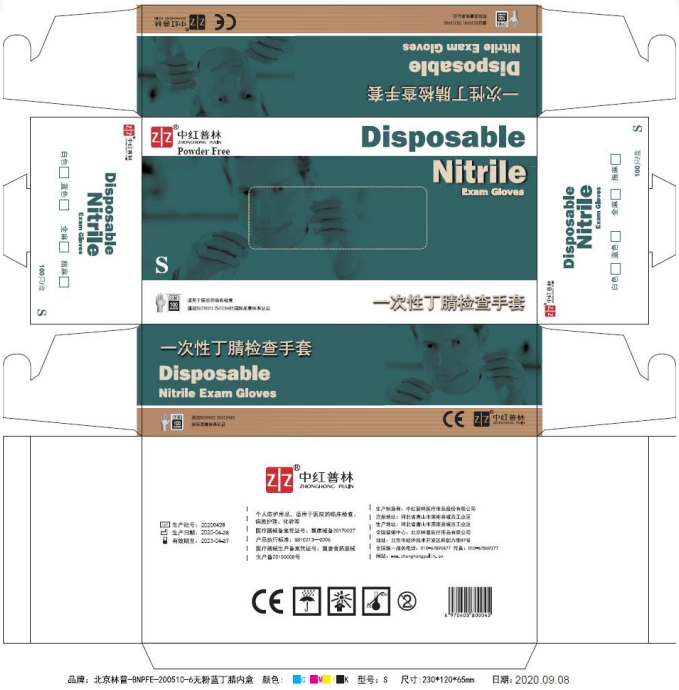

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

PSB Singapore

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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

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

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	M	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

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
No.1 Science Park Drive
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Co. Reg : 199002667R

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

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

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; - 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 5.3 shall be given.	NA
		Inferred results	Passed

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 Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

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

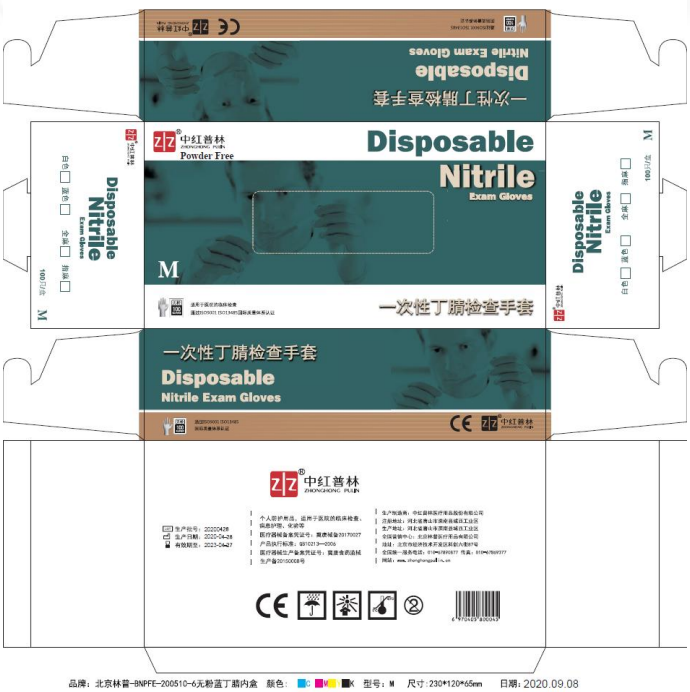

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

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Effective 01 September 2020

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

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	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

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TÜV SÜD PSB Pte. Ltd.
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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
TÜV®

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

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; - 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 5.3 shall be given.	NA
		Inferred results	Passed

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 Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

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

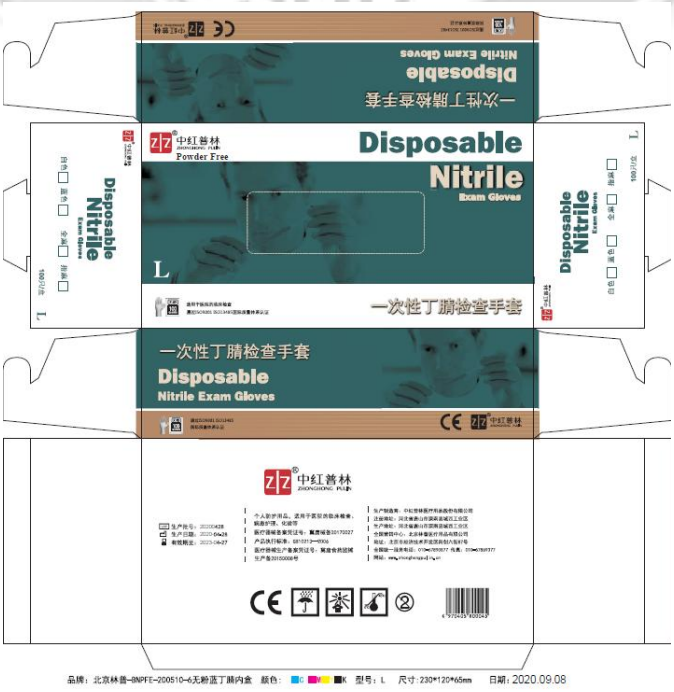

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

PSB Singapore

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Effective 01 September 2020

Test Report No. 7191240823-EEC20/04-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	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

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

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 5.3 shall be given.	NA
		Inferred results	Passed

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 Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

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

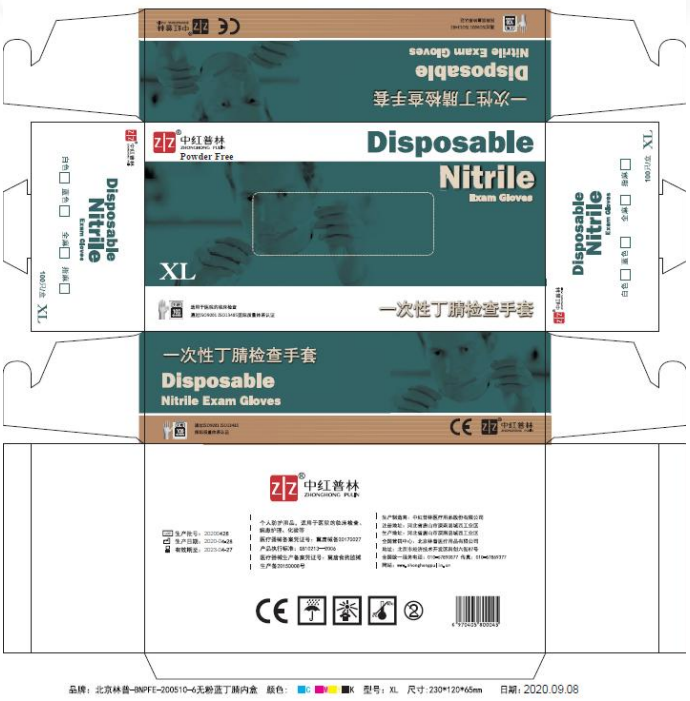

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

PSB Singapore

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Effective 01 September 2020