Test Report No. 7191267913-EEC21/03-WBH
dated 16 Sep 2021

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SUBJECT

Testing of Gloves

CLIENT

Shijiazhuang Hongray Group Co.,Ltd.
South Tongda Rd., East Dist.,
Jinzhou City, Hebei,
052260, China

SAMPLE SUBMISSION DATE

(1) 20 Apr 2021
(2) 07 Jun 2021

TEST DATE

(1) 20 Apr 2021 to 18 May 2021
(2) 07 Jun 2021 to 28 Jun 2021

DESCRIPTION OF SAMPLES

S/N	Product Description	Brand/ Model	Colour	Lot No.	Size	Sample Received (pieces)	Manufacturer
1	Disposable Nitrile Examination Gloves	Hongray	Blue	-	S	400	Shijiazhuang Hongray Group Co.,Ltd.
2					M	400	
3					L	400	
4					XL	400	

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

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

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RESULTS

Sample: Disposable Nitrile Examination Gloves, Hongray, Blue

Table 1: Results for EN 455-1:2020

Clause	Tests	Size	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	S	Shall not leak	10	315	2	Passed
		M		10	315	6	Passed
		L		10	315	4	Passed
		XL		10	315	9	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Size	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	S	≥ 240	13	243	Passed
		M		13	246	Passed
		L		13	242	Passed
		XL		13	244	Passed
	b) Width (mm)	S	80 ± 10	13	83	Passed
		M	95 ± 10	13	95	Passed
		L	110 ± 10	13	104	Passed
		XL	≥ 110	13	114	Passed
5	Strength a) Force at break (N)	S	For nitrile examination gloves: ≥ 6.0	13	6.3	Passed
		M		13	7.5	Passed
		L		13	6.3	Passed
		XL		13	6.7	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	S	For nitrile examination gloves: ≥ 6.0	13	6.1	Passed
		M		13	7.8	Passed
		L		13	6.2	Passed
		XL		13	6.5	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: Disposable Nitrile Examination Gloves, Hongray, Blue

Table 4: Results for EN 455-3:2015 Clauses 4.2-4.5

Clause	Tests	Requirements	Results / Remarks		Inferred results
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is not dressed with talcum powder, based on client's declaration letter		Passed
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients		NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'		NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	S	0.43 mg per glove	Passed
			M	0.65 mg per glove	Passed
			L	0.40 mg per glove	Passed
			XL	0.17 mg per glove	Passed
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Not natural rubber latex glove		NA

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

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REMARKS

1. This report is a consolidated version of issued reports – (i) 7191258457-EEC21-WBH and (ii) 7191263435-EEC21-WBH.
2. The Product Description was changed to “Disposable Nitrile Examination Gloves” in this report from “Disposable Nitrile Gloves” as mentioned in remark (1), item (i & ii) on the basis of the declaration by the client that the product is exactly the same.
3. Lot No. was not provided by client.
4. Unless otherwise stated, all tests were conducted using samples received on 20 Apr 2021.
5. Dimensions and Strength test for size M (see Table 2, page 2 of this report) were conducted using samples received on 07 Jun 2021.
6. Manufacture has declared that the all samples received are from the same production lot, with same material and same process.
7. Labelling requirements are assessed based on submitted packaging artwork by client.
8. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate BS ENgineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX

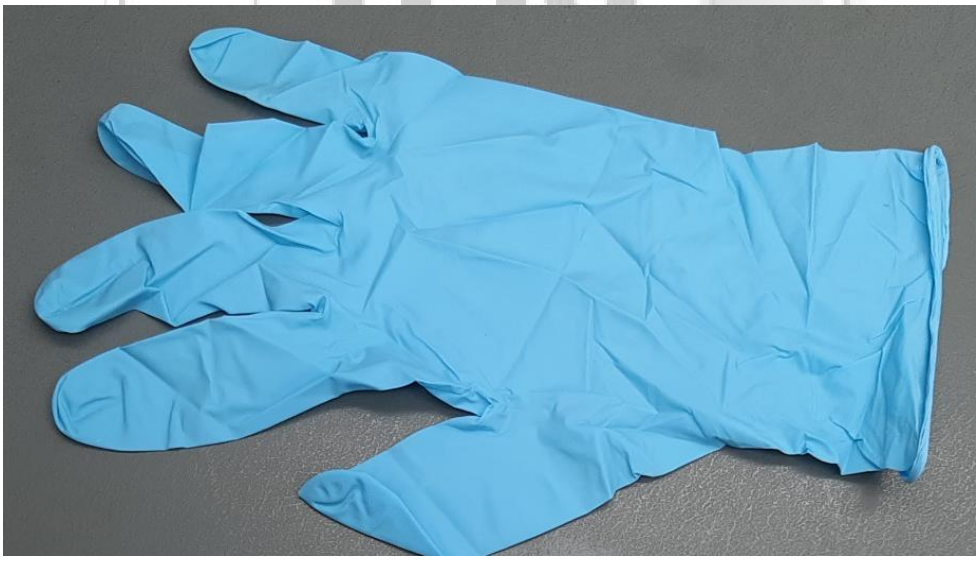

Photo: Disposable Nitrile Examination Gloves, Hongray, Blue

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Effective 26 January 2021