Test Report No. 7191246148-EEC20/03d-LDY
dated 20 Nov 2020

PSB Singapore

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SUBJECT:

Testing of Gloves submitted by Lanhuo Medical Technology (Shanghai) Co., Ltd on 12 Oct 2020.

TESTED FOR:

Lanhuo Medical Technology (Shanghai) Co., Ltd
Room B, Second Floor,
Building 22, 189 Jinglian Road,
Minhang District, Shanghai, China

TEST DATE:

12 Oct 2020 to 07 Nov 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Product Code	Brand/ Model	Colour	Lot No.	Size	Sample Received (pieces)	Manufacturer
1	Disposable Nitrile Multi-Purpose Gloves	LHEMB	- (see Remark 1)	Blue	202000106598	L	408	Lanhuo Medical Technology (Jiangsu) Co., Ltd

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

METHOD OF TEST:

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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RESULTS:

Sample: Disposable Nitrile Multi-Purpose Gloves, Blue, Size L

Table 1: 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.	1.32 mg per glove	Passed

Table 2: 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. The Brand/Model was not provided by client.
2. Labelling requirements are assessed based on the submitted packaging artwork by client.
3. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Lee Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

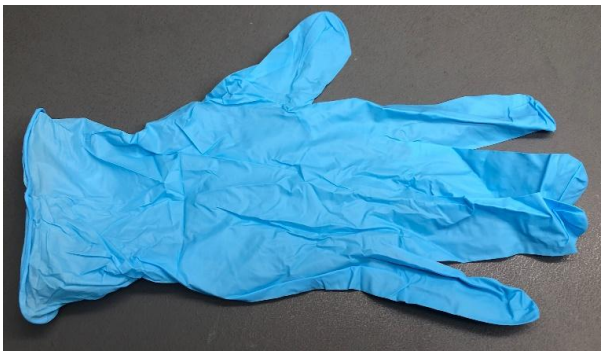

Photo 1: Disposable Nitrile Multi-Purpose Gloves, Blue, Size L

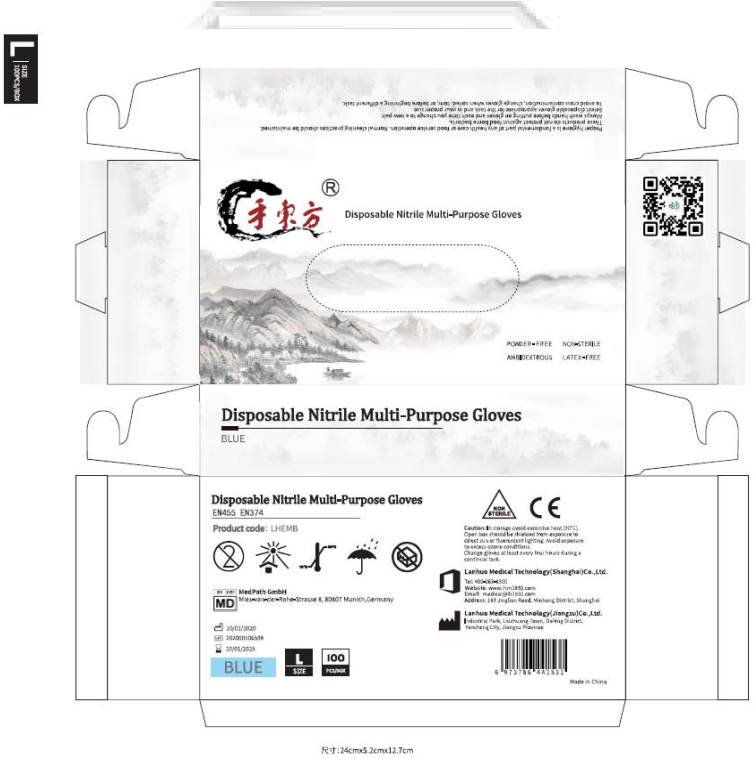

Photo 2: Packaging artwork for Disposable Nitrile Multi-Purpose Gloves, Blue, Size L

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Effective 01 September 2020