

Test Report No. 7191100117-EEC14-CSL_CR1
dated 12 Nov 2014



PSB Singapore

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SUBJECT:

Testing of Powder-free Nitrile Examination Gloves submitted by Adventa Health Sdn Bhd on 29 Oct 2014.

TESTED FOR:

Adventa Health Sdn Bhd
No. 1, Jalan 8, Pengkalan Chepa 2 Industrial Zone,
Kotabharu,
16100 Kelantan.

TEST DATE:

29 Oct 2014 to 11 Nov 2014

DESCRIPTION OF SAMPLES:

S/N	Product Description	Lot No.	Colour	Size	Sample received (pieces)	Manufacturer
1	Nitrile examination gloves	2435520	Blue	M	5 boxes (100 pieces per box)	Adventa Health

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

METHOD OF TEST:

1. EN 455-1:2000 Medical gloves for single use
Part 1: Requirements and testing for freedom from holes
2. EN 455-2:2009+A2:2013 Medical gloves for single use
Part 2: Requirements and testing for physical properties
3. EN 455-3:2006: Medical glove for single use
Part 3: Requirements and testing for biological evaluation
- Clause 4.4 Powder
- Clause 4.6 Labelling

Amendments:

The following amendment was made on 30 Mar 2015:
The Photograph under "APPENDIX" was replaced as requested.



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RESULTS:

Sample: Nitrile examination gloves (Size M) – Lot no.: 2435520

Table 1: Results for EN 455-1

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	1	Passed

Table 2: Results for EN 455-2

Clause	Tests	Requirements	Number tested (pieces)	Median	Inferred results
4	a) Length (mm)	Median Length for size M: ≥ 240	13	245	Passed
	b) Width (mm)	Median Width for size M: 95 ± 10	13	96	Passed
5	a) Force at break (N)	Median Force at Break for nitrile examination gloves: ≥ 6.0	13	8.7	Passed
	b) Force at break after challenge testing (N)	Median Force at Break for nitrile examination gloves: ≥ 6.0	13	8.9	Passed


Table 3: Results for EN 455-3 Clause 4.4

Clause	Tests	Requirements	Number tested	Results	Inferred results
4.4 5.2	Powder	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	5 pieces	1.3 mg per glove	Passed

RESULTS:

Sample: Nitrile examination gloves (Size M) – Lot no.: 2435520

Table 4: Results for EN 455-3 Clause 4.6

Clause	Tests	Requirements	Results	Inferred results
4.6	Labelling	In addition to the labelling specified in EN 1041 and the relevant symbols given in EN 980 (replaced by EN ISO 15223-1), the following requirements apply:		Passed
		a) medical gloves containing natural rubber latex shall be labelled at least on the packaging, of the smallest packaging unit with the following symbol; 	a) NA	
		b) 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';	b) NA	
		c) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	c) Observed	
		d) 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';	d) NA	
		e) 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;	e) NA	
f) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	f) NA			


Shareen Chan
Engineer


Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:



Photo : Nitrile examination gloves (Size M) – Lot no.: 2435520

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July 2011

