

CRANBERRY EVOLVE NITRILE DISPOSABLE GLOVES SPECIFICATION AND CERTIFICATION



CRANBERRY EVOLVE

SPECIFICATIONS

Recommended for use when:

- i) A latex-free, powder-free solution is required.
- ii) Seeking a soft and tear-resistant, protective solution with good grip.
- iii) Seeking space-saving, reduced waste packaging.

Physical Data					
Dimension	Extra-Small	Small	Medium	Large	Extra-Large
Length (mm) min.	230	230	230	230	230
Palm Width (mm)	70±10	80±10	95±10	110±10	120±10
Thickness (mm) min.					
~ Finger	0.05	0.05	0.05	0.05	0.05
~ Palm	0.05	0.05	0.05	0.05	0.05
~ Cuff	0.04	0.04	0.04	0.04	0.04
Tensile Strength (MPa), min					
~ Unaged	16	16	16	16	16
~ Aged	16	16	16	16	16
Elongation (%), min					
~ Unaged	500	500	500	500	500
~ Aged	400	400	400	400	400

Single Use Only, Ambidextrous, Non-Sterile

Packaging: 300 gloves/box, 10 boxes/case; XL: 250 gloves/box

XS (3305) **M** (3307) **XL** (3309)

S (3306) **L** (3308)

GLOVE COMPARISONS

Medical gloves are usually made from polymers such as latex, vinyl and nitrile, although you may find disposable gloves made of other materials, such as neoprene. The following is a quick comparison of nitrile vs. latex vs. vinyl gloves, including the differences in design and their unique benefits. We have dedicated dipping line for R&D work. This special facility enables new product development and prototyping to be carried out in the shortest time possible.

GLOVE TYPE	DEFINITION	ADVANTAGE	PROTECTION LEVEL
Latex Gloves	Made of natural rubber	Highest comfort, flexibility, fit and tactile sensitivity	Bacteria, viruses
Nitrile Gloves	Made of synthetic material	Stretchy, durable	Chemicals, viruses
Vinyl Gloves	Made of synthetic material, sometimes referred to as synthetic	Cost-efficient synthetic option, comfortable	Chemicals

LATEX GLOVES VS. LATEX-FREE GLOVES

Latex gloves are often preferred by healthcare providers since they provide the best service when it comes to elasticity, comfort and fit. Surgeons benefit from latex gloves since they are great for sensitive work, since they offer more precision with high tactile sensitivity.

Despite its advantages, latex gloves have become an issue for many health professionals due to the increasing rate of latex allergies, and many are choosing to go with non-latex glove options such as vinyl and nitrile gloves instead.

Vinyl gloves, which are made from PVC (polyvinyl chloride), are usually the cheapest latex-free gloves. However, many prefer to use higher-end gloves such as nitrile gloves. Nitrile gloves are often preferred since these non-latex gloves best resemble the stretchy feel of latex gloves and are also highly durable and puncture resistant.

Another difference to consider when deciding between latex and latex-free gloves is the protection offered by each type of material. In general, latex gloves offer the best protection against bacteria and viruses, while synthetic gloves provide better chemical protection. Of the different types of latex-free gloves, nitrile gloves offer a higher degree of protection against viruses, besides the chemical protection they provide.

CRANBERRY EVOLVE

TEST REPORT

Test Report No. 719 [REDACTED]
dated 23 Mar 2018



PSB Singapore

RESULTS:

Sample: Powder Free Nitrile Examination Gloves, BS0002

Table 1: Results for EN 455-1:2000

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	XS	Shall not leak	10	315	1	Passed
		S		10	315	1	Passed
		M		10	315	2	Passed
		L		10	315	6	Passed
		XL		10	315	4	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)	XS	≥ 240	13	250	Passed
		S		13	250	Passed
		M		13	255	Passed
		L		13	250	Passed
		XL		13	248	Passed
	b) Width (mm)	XS	≤ 80	13	73	Passed
		S	80 ± 10	13	85	Passed
		M	95 ± 10	13	96	Passed
		L	110 ± 10	13	106	Passed
		XL	≥ 110	13	115	Passed
5	Strength a) Force at break (N)	XS	For nitrile examination gloves: ≥ 6.0	13	6.4	Passed
		S		13	8.6	Passed
		M		13	6.1	Passed
		L		13	6.1	Passed
		XL		13	6.6	Passed
	b) Force at break after challenge testing (N)	XS	For nitrile examination gloves: ≥ 6.0	13	7.0	Passed
		S		13	9.0	Passed
		M		13	7.3	Passed
		L		13	6.6	Passed
		XL		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

CRANBERRY EVOLVE

TEST REPORT

Test Report No. 7191 [REDACTED]
dated 23 Mar 2018



PSB Singapore

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Powder Free Nitrile Examination Gloves submitted by [REDACTED] o., Ltd. on 25 Jan 2018 and 09 Mar 2018.

Choose certainty.
Add value.

TESTED FOR:



TEST DATE:

26 Jan 2018 to 06 Feb 2018 and 22 Mar 2018

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Reference No.	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Powder Free Nitrile Examination Gloves	Blue	BS0002	12150511	XS	100	[REDACTED] Ltd.
				03060511		69	
				12150521	S	100	
				12080311	M	100	
				12090411	L	100	
				12070611	XL	407	

Lot size as specified by client: 200,000 pieces

METHOD OF TEST:

- EN 455-1:2000 Medical gloves for single use
Part 1: Requirements and testing for freedom from holes
- EN 455-2:2015 Medical gloves for single use
Part 2: Requirements and testing for physical properties
- EN 455-3:2015 Medical glove for single use
Part 3: Requirements and testing for biological evaluation



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CRANBERRY EVOLVE

TEST REPORT

Test Report No. 7191 [REDACTED]
dated 23 Mar 2018

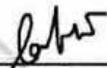


PSB Singapore

REMARKS:

1. Freedom from holes test for XS, S, M and L sizes were tested in manufacturer's site, witnessed by TÜV SÜD Certification and Testing (China) Co., Ltd. Beijing Branch on 22 Mar 2018.
2. For size XS, results for EN 455-2:2015 Clause 4 Dimensions is based on lot no. 03060511, while the rest of the results are based on lot no. 12150511.
3. Labelling requirements are assessed based on submitted packaging artwork together with client's declaration letter version number 2018003.
4. NA: Not applicable for the submitted sample.


Shareen Chan
Engineer


Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:



Photo : Powder Free Nitrile Examination Gloves, BS0002

CRANBERRY EVOLVE

CERTIFICATES



Issued to:



Notified Body: 2777

SATRA customer number:



EU Type-Examination Certificate

Certificate number: 2777/



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:

- Clear – 697024575 XXX
- Yellow – 697024575 XXX
- Blue – 697024575 XXX
- White – 697024575 XXX

Description:

Disposable vinyl Powdered and Powder-Free, non-sterile gloves

Size	Blue	White	Clear	Yellow
6 XS	221	231	201	211
7 S	222	232	202	212
8 M	223	233	203	213
9 L	224	234	204	214
10 XL	225	235	205	215

Classification:

- EN ISO 374-1:2016/Type B**
- Sodium Hydroxide 40% (K)
- Hydrogen peroxide 30%(P)
- Formaldehyde 37% (T)
- EN ISO 374-5:2016**
- Protection against bacteria and fungi
- Protection against viruses

Level	Degradation %
6	-19.9
2	22.1
3	19.2
Pass	
Pass	

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN 388:2016; EN ISO 374-1:2016; EN ISO 374-5:2016

Technical reports/Approval documents:
SGS: CH:TX:7420016049, CH:TX:7420016055, QDHL1703003987OT, QDHL1703003988OT, CH:TX: 6420028491-1, CH:TX:9420028490, CH:TX:1042061966, CH:TX:1042059408
SATRA: CHT0272448/1814, CHT0285339/1921, CHT0280247/1903
TUV: 721642857-1, 719223458-EEC19-WBH_CR1, 7191221099-CHM19-TSL

Signed on behalf of SATRA.

Anita Brennan

Anita Brennan

Jacque Glasspool

Jacque Glasspool

Date first issued: 06/08/2018
Date of issue: 09/01/2020

Expiry date: 06/03/2023

CRANBERRY EVOLVE

CERTIFICATES



PPE REGULATION (EU) 2016/425 MODULE C2 CERTIFICATE

Issued to:



This is to certify that the following products tested under SATRA reports referenced: [REDACTED]
[REDACTED] have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2
EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
2777/ [REDACTED]	BS01020X	Disposable medical Nitrile examination glove	EN ISO 374-1:016

Dated: 14th November 2019 This certificate is valid until: November 2020

Signed By (Alan Weston)

For and on behalf of SATRA Technology
Europe Limited



The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard.

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