HISTORY

Since 1988, we have specialized in the development, manufacturing, and distribution of protective infection control solutions.

At Cranberry, we stress utmost importance on providing products of superior quality. Therefore, we constantly strive to develop products with the highest protection, comfort, and strength. After thriving in this industry for so many years, we truly understand your needs and demands as a professional. Be assured that our dynamic team is always moving forward, researching, and seeking to provide you with only the best.

We have established successful partnerships in many countries. Even so, we are excited to expand our networks and distribution further so that Cranberry gloves are made available in every country.

As a professional, you are passionate about the health and comfort of your clients. At Cranberry, we are passionate about yours.

Cranberry Nitrile Gloves Standard Operating Procedure

1. Sign NCNDA agreements followed by LOI and POF

2. SELLER to respond to LOI with models, pricing and quantity. (Note: models available will be determined on a case by case basis)

3. Draft SLA/SPA-conditions to be reviewed by BUYER. If totally in agreement, continue to the next stage.

4. The BUYER will send an ICPO to the SELLER or to a company as directed by the SELLER (Numeric Advisory). BUYER to specify exact model, pricing and quantities of each size in the ICPO

5. The SELLER will submit a pro-forma invoice to the BUYER.

6. Bank Guarantee/LC/Escrow must be set up to move to the next stage. NOTE: No videos or proof of life will be provided in this process.

7. The BUYER will accept the proforma invoice and both parties will sign a service level agreement (SLA/SPA).

8. 10% will be deposited into a mutually agreed facility to commit to the transaction.

9. SGS certificates will be made available 48 to 72 hrs after the order has been placed. The certificate will indicate that the stock will meet the regulated requirements. Delivery schedule is provided.

10. A waybill will be issued to the BUYER informing them that the stock is in transit.

11. Once the stock lands, the stock will be viewed by the BUYER and the SELLER and the remaining 90% of the funds will be released to the SELLER

12. The SELLER will transfer the SGS certificate to the name of the BUYER.

13. The BUYER then owns the stock and is responsible for any fees and costs thereafter.

14. The BUYER's agents will clear this through customs.

15. We would highly recommend that the appropriate transportation, security, and insurance is arranged by the BUYER.

16. This is a CIF transaction.

FIRST TOUCH

In an average manufacturing process, gloves and masks may come in human skin contact up to 8 times. With ultimate hygiene in mind, Cranberry products are First Touch® manufactured, examined, and packaged with zero direct skin contact exposure. Don't just put on any gloves and masks, look for our First Touch® logo and be assured that you are doing the best you can to protect yourself and your patients.

CERTIFICATIONS

Quality Managment Systems

ISO 13485 & ISO 9001

Test Report No. 7191
dated 23 Mar 2018

PSB Singapore

Choose certainty.
Add value.

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
o., Ltd. on 25 Jan 2018 and 09 Mar 2018.

TESTED FOR:

, Shandong,
China.

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	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:

1. EN 455-1:2000 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

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
No.1 Science Park Drive
Singapore 118221

Phone : +65-6885 1333
Fax : +65-6776 8670
E-mail: enquiries@tuv-sud-psb.sg
www.tuv-sud-psb.sg
Co. Reg. : 199002667R

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

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

RESULTS (cont'd):

Sample: Powder Free Nitrile Examination Gloves, BS0002

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 powder-free glove, based on client's declaration letter version 2018001		NA
		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.	XS	0.61 mg per glove	Passed
			S	0.63 mg per glove	Passed
			M	0.97 mg per glove	Passed
			L	0.86 mg per glove	Passed
			XL	0.48 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.	Non-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

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:

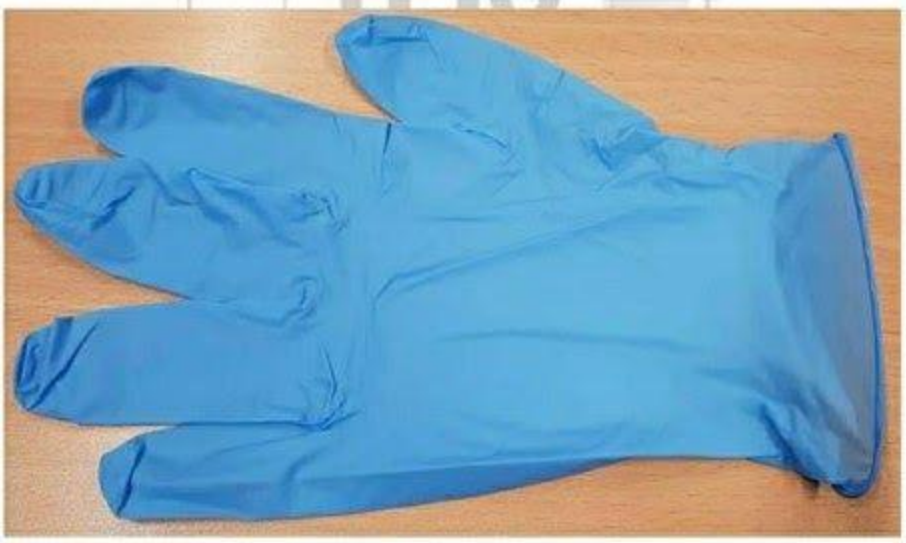


Photo : Powder Free Nitrile Examination Gloves, BS0002

PPE REGULATION (EU) 2016/425
MODULE C2 CERTIFICATE

Issued to:

Blue Sail Medical Co Ltd
Qilu Chemical Industrial Park
No 21 Qingtian Road
Zibo
Shandong
China

This is to certify that the following products tested under SATRA reports referenced:CHM0291439/1944/JH & STE0289547 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
2777/11521-01/E00-00	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

CE

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

SATRA Technology Europe Limited. Bracetown Business Park Clonee Dublin 15 D15 YN2P. Republic of Ireland.
(Notified Body number 2777)
Tel: +353 (0) 1 437 2484 Web: www.satraeurope.com

510(k) Premarket Notification

Device Classification Name	Polymer Patient Examination Glove
510(K) Number	K983334
Device Name	NITRILE POWDER FREE EXAMINATION GLOVES
Applicant	CRANBERRY (M) SDN. BHD. LOT 85, JALAN PORTLAND, TASEK INDUSTRIAL ESTATE Ipoh Perak, MY 31400
Applicant Contact	Chong Yoon Tat
Correspondent	CRANBERRY (M) SDN. BHD. LOT 85, JALAN PORTLAND, TASEK INDUSTRIAL ESTATE Ipoh Perak, MY 31400
Correspondent Contact	Chong Yoon Tat
Regulation Number	880.6250
Classification Product Code	LZA
Date Received	09/23/1998
Decision Date	02/19/1999
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Statement	Statement
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1999

Mr.**********
Director
Cranberry (M) Sdn. Bhd.
****
****
****
MALAYSIA

Re: K983334
Trade Name: Nitrile Powder-Free Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: January 15, 1999
Received: January 19, 1999

Dear Mr. **********

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CRANBERRY (M) SDN. BHD. (104994 - W)
(A MEMBER OF THE YEE LEE GROUP)

Applicant : CRANBERRY (M) SDN. BHD.
****
****
****

510(k) Number (if known): K*83*3*

Device Name: Nitrile Powder Free Examination Glove - Cranberry

Indications For Use:

This product is a patient examination glove. It is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lin
(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) N K98****

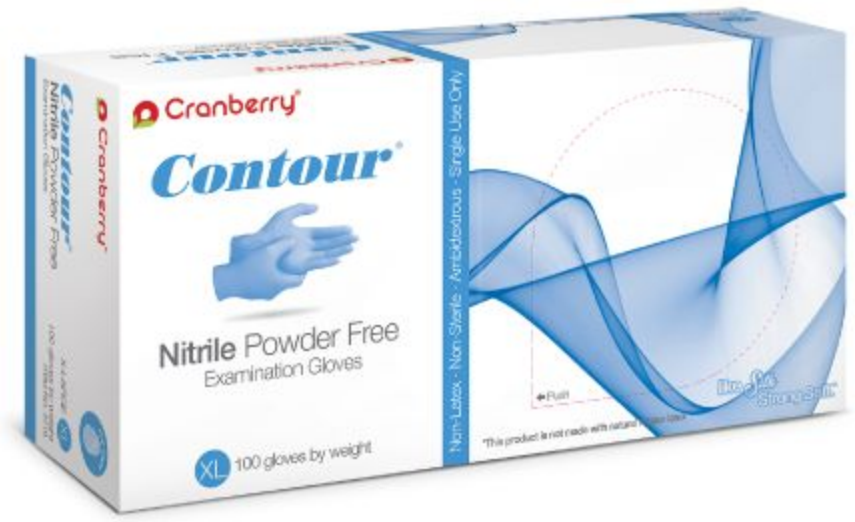
Prescription Use_____ OR Over-The-Counter-Use X
(Per 21 CFR 801.109)

C

Contour®

Nitrile Powder Free
Examination Gloves

Contour is body heat activated to contour ergonomically for reduced hand fatigue during periods of extended wear. In addition, the gloves provide latex-like comfort and superior donning efficiency. Available in blue, the gloves are packed 100 pieces per box.

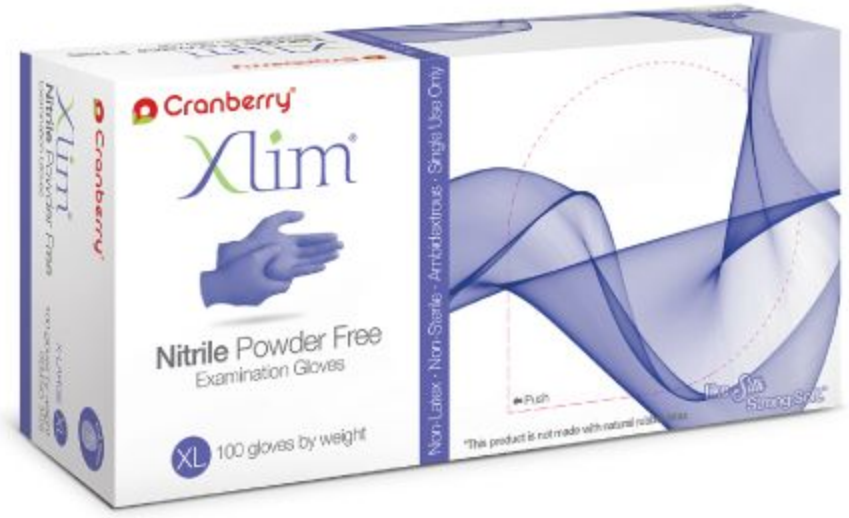


Xlim®

Nitrile Powder Free

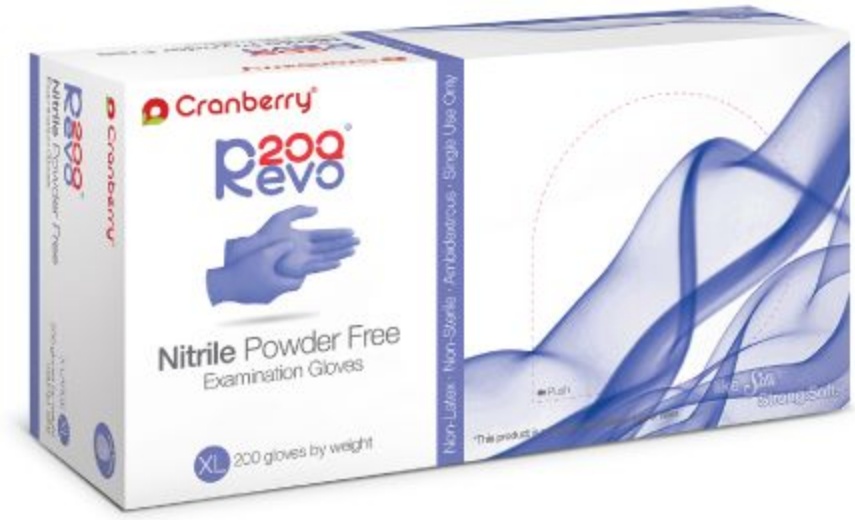
Examination Gloves

Cranberry Xlim nitrile gloves provide the ultimate protection with 30% higher tensile strength for stronger and greater tear resistance. Its exclusive 7th Sense™ formulation softens with body heat and improves barrier protection against viral penetration.



Revo200 Nitrile Powder Free Examination Gloves

Revo200 Nitrile was our first glove with 200 pieces per box. It's RevoSoft™ formulation provides unprecedented softness and comfort, all with superior tensile strength.

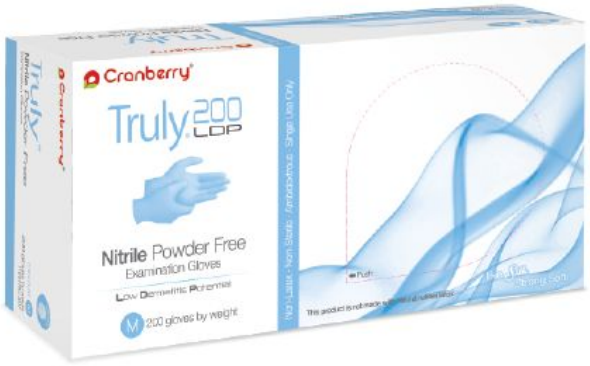


Truly 200 LDP

Nitrile Powder Free
Examination Gloves

Truly 200 LDP is the 1st FDA cleared glove with low dermatitis potential and chemotherapy drug tested claim in the dental industry. The gloves are specifically engineered as accelerator-free with innovative manufacturing approach to reduce the potential of Type I & Type IV allergic reactions. Truly 200 LDP formulation offers maximum stress-free comfort and greater tensile strength to prevent tearing.

- FDA cleared low dermatitis claim greatly reduces incidence of contact dermatitis
- Accelerator-Free nitrile reduces Type I & Type IV allergic reactions
- Chemotherapy drug permeation tested for resistance to penetration by select drugs
- 200 Saver Pack to reduce costs and storage space
- Exclusive SmartGrip® technology deliver optimal wet grip performance

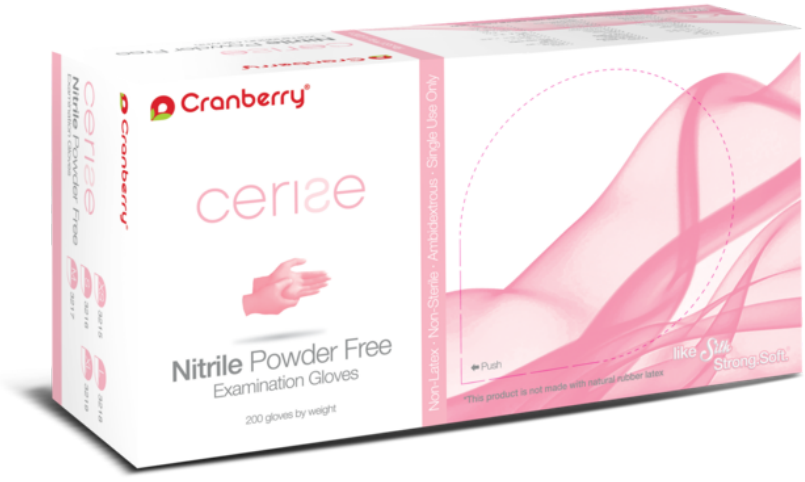


cerise®

Nitrile Powder Free
Examination Gloves

***Available in non-U.S. markets only**

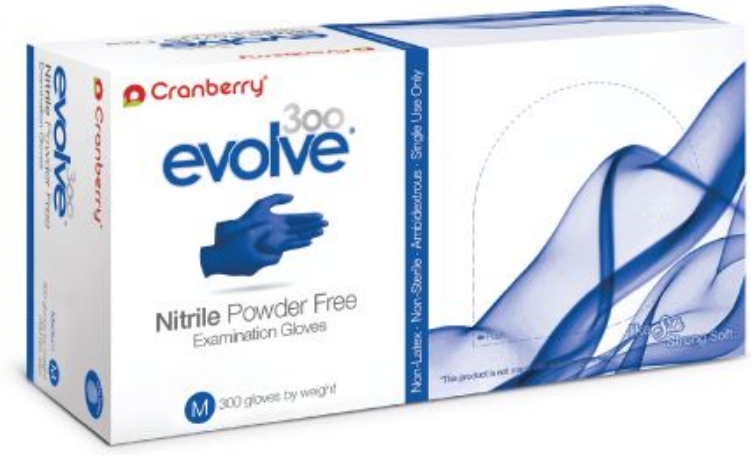
Cerise® Nitrile gloves feature our very first distinct pink color with proprietary formulation that provides comfort and performance and anti-slip grip provides secure handling in wet and dry conditions. 200-count Saver Pack reduces storage space and packaging waste.



evolve 300

Nitrile Powder Free Examination Gloves

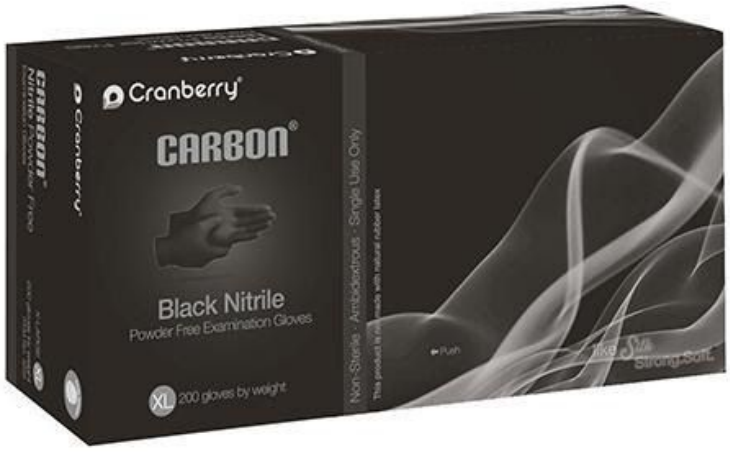
The Evolve 300 Nitrile Powder Free Examination Gloves are Cranberry's latest and softest gloves yet, combining comfort and tensile strength without sacrificing tactile sensitivity. Cranberry's exclusive EvoSoft™ formulation gives Evolve a unique silk-like attribute that is both soft and strong with textured fingertips for precise gripping under all operating conditions.



CARBON®

Nitrile Powder Free
Examination Gloves

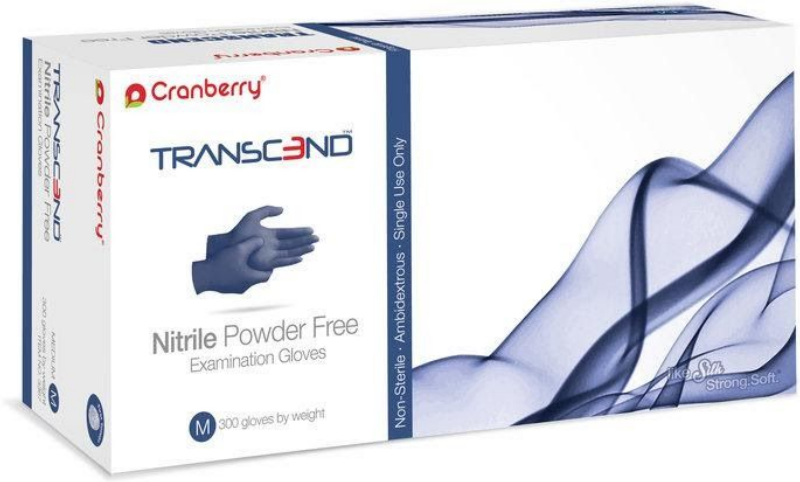
Carbon® Nitrile gloves feature distinct black color to minimize visible stains during use, enhanced fingertip texture for superior handling and increased control. 200-count Saver Pack reduces storage space and packaging waste.



TRANSC3ND™

Nitrile Powder Free
Examination Gloves

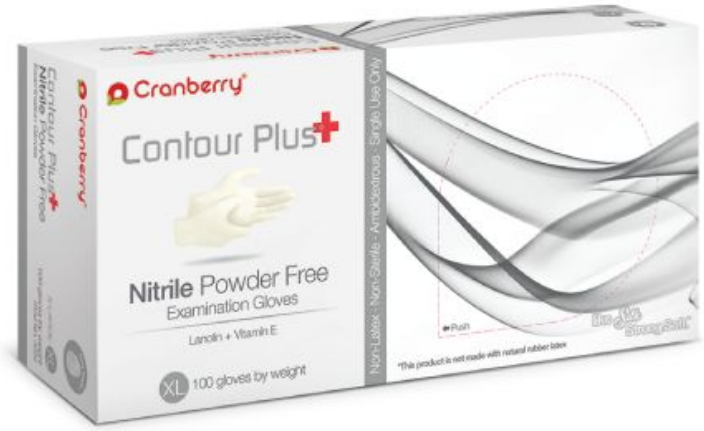
The Transcend Nitrile Powder Free Examination Gloves are Cranberry's latest and strongest gloves yet, uncompromised superior formulation for high tensile strength without sacrificing tactile sensitivity that is both soft and strong with textured fingertips for precise gripping in dry and wet conditions. The latest Patented Low Derma Technology eliminates the chemical accelerators commonly found in nitrile, reducing the risk of Type I & Type IV hypersensitivities.



Contour Plus

Nitrile Powder Free
Examination Gloves

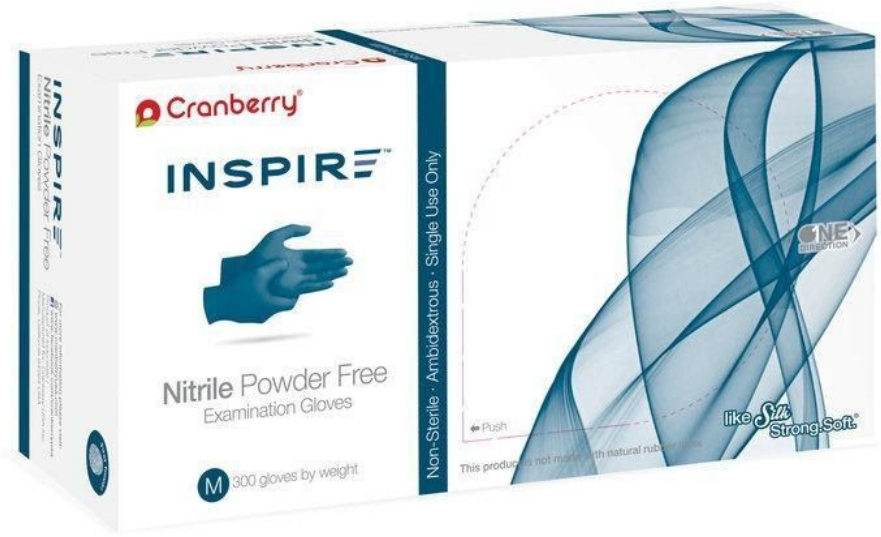
Contour Plus® is our first nitrile exam glove with lanolin & vitamin E coating. Its NuComfort® formulation provides unmatched sensitivity, flexibility, easy donning, and superior comfort.



INSPIRE™

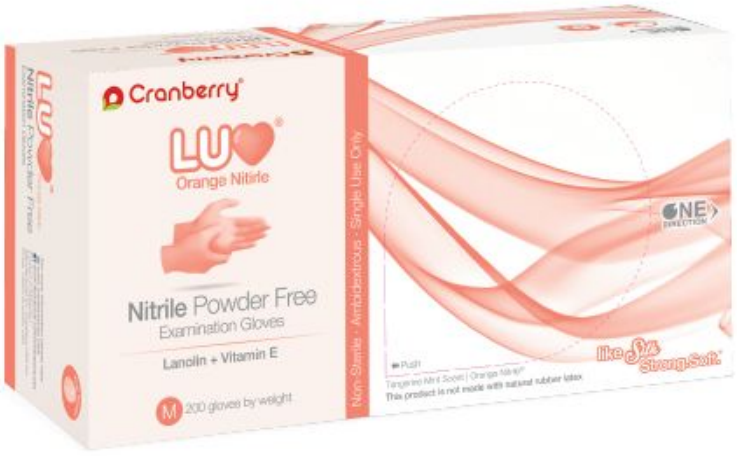
Nitrile Powder Free Examination Gloves

Experience Cranberry’s fittest and lightest gloves yet! Inspire Nitrile gloves feature distinct aegean blue color to minimize visible stains during use, enhanced fingertip texture for superior handing and increased control. Our exclusive InSoft™ formulation provides increased soft comfort. 300-count Saver Pack reduces storage space and packaging waste.



Orange Nitrile Powder Free Examination Gloves

You will fall in "LUV" with this orange nitrile color and mild tangerine-mint scented glove. LUV also features our skin-pampering NuSoft™ formulation with Lanolin and Vitamin E.

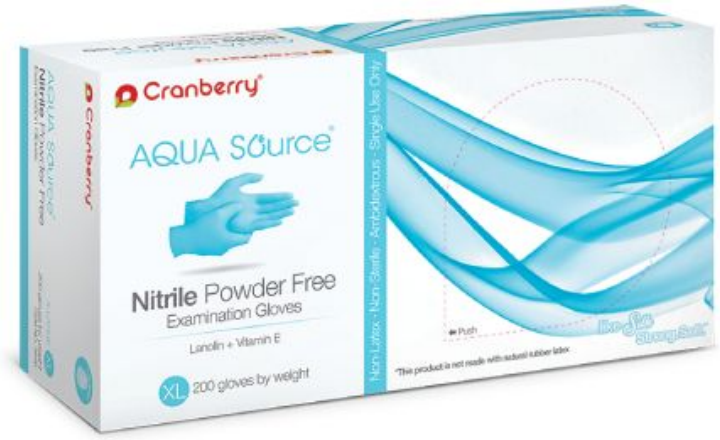


AQUA Source

Nitrile Powder Free

Examination Gloves

Aqua Source is coated with Lanolin and Vitamin E to minimize dry skin irritation associated with constant glove changing. Complete with full hand texturing and ultra-thin feel for superior tactile sensitivity and grip. Aqua Source is packaged in an economical and space-saving 200-count box.



LUXE™

Nitrile Powder Free
Examination Gloves

Soft and luxurious. LUXE nitrile, the first 300 count coated gloves in the market, is our newest powder free nitrile gloves packed with our exclusive blend of Lanolin and Vitamin E. This formulation is clinically proven to maximize moisture retention that prevents dryness, itching, and cracked skin.