MICRO-TOUCH® Nitrile Accelerator-Free

High Touch

Nitrile, powder-free examination glove with advanced allergy prevention

This non-sterile accelerator-free offers a solution for those who suffer from chemical Type IV allergies. A comfortable fit and feel with micro-textured fingers ensure a secure and safe grip in wet or dry conditions.

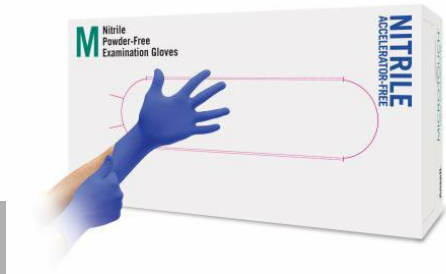
KEY FEATURES AND BENEFITS:
• Provides a high-level of barrier protection against punctures as well as excellent resistance from a broad range of commonly used chemicals.
• Chlorinated inner surface for easy donning
• Protects from latex Type I allergy
• 100% thiuram-free formulation significantly reduces the risk of Type IV allergies.

WARNING: No glove completely protects against all chemicals. Users should test the suitability of this product against the specific chemicals and environment where used.

Recommended For

- Tested for use with chemotherapy drugs
- Enhanced tactile sensitivity and dexterity, especially for delicate procedures
- Protection from latex Type I allergy and minimize chemical Type IV allergies in HCW's or patients
- Standard patient examinations

FEATURED TECHNOLOGIES



MICRO-TOUCH® Everyday, Everywhere Protection

MICRO-TOUCH® premium medical examination gloves are scientifically designed to complement every need of medical professionals. Sophisticated design features include Ansell ergonomic technologies that ensure comfort during extended procedures, wet grip innovations that prevent harmful mishandling, and micro-thin films for maximum sensitivity. Caregivers who are fully prepared and comfortably protected by versatile MICRO-TOUCH styles have the peace of mind to focus on what matters most: the health and protection of themselves and their patients.

MICRO-TOUCH® Nitrile Accelerator-Free

High Touch

PRODUCT INFORMATION			
Material	Nitrile	**Not Made From Natural Rubber Latex**	Yes
Color	Blue	**Cuff Length**	Standard
Powder Content	Powder-Free	**External Glove Surface**	Textured Fingers
Freedom from Holes (Inspection level I)	1.5 AQL	**Palm Thickness (mm/mil)**	0.08 / 3.1
Finger Thickness (mm/mil)	0.12 / 4.7	**Allergy Prevention**	Latex (Type I), Chemical (Type IV)
Available Sizes	XS (5.5 - 6), S (6.5 - 7), M (7.5 - 8), L (8.5 - 9), XL (9.5 - 10)	**Tested For Use With Chemotherapy Drugs**	Yes, in accordance with ASTM D6978 (Not listed in the US FDA 510k)
Sterile	No	**Antistatic**	Not Tested
Glove Length (mm/inches)	240 / 9.5	**Product Segmentation**	High Touch

ORDERING INFORMATION					
Size	**XS (5.5 - 6)**	**S (6.5 - 7)**	**M (7.5 - 8)**	**L (8.5 - 9)**	**XL (9.5 - 10)**
Product Code	700101	700102	700103	700104	700105

PACKAGING AND STORAGE	
Packaging	100 gloves per dispenser 10 dispensers per case 1000 gloves per case
Shelf Life	5 Years
Storage Instructions	Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.

STANDARDS AND CERTIFICATIONS

Category III, EN 374:2003, EN 420:2003 + A1:2009, EN 421:2010, EN 455 1-4, EN ISO 374-1:2016, EN ISO 374-5:2016, ISO 13485, ISO 10993-10:2002

Contact your Ansell representative for ordering or more information.

North America
US Tel: 800 952 9916
CA Tel: 1-844-494-7854
Email: insidesalesus@ansell.com

Latin America & Caribbean
Tel: +52(442) 296 20 50
Email: cslac@ansell.com
Brazil Tel: +55-11-3356-3100
Brazil Email: luvas.medicas@ansell.com

Europe, Middle East & Africa
Tel: +32 (0) 2 528 74 00
Email: info@ansell.eu

Asia Pacific
Tel: +603 8310 6688
Email: apac.medical@ansell.com

Australia & New Zealand
Tel: +61 3 9270 7270
Email: protection@ap.ansell.com

ANSELL SINGLE USE GLOVES – CAT. III EN

A. Use - Gloves are designed to protect the hands mainly against chemical splash risks and comply with the harmonised standards shown by pictograms. **Explanation of symbols & pictograms:**

CE PPE-XXXX MDD XX/XX	Medical Device Class I under MDD 93/42/EEC and PPE protecting against Cat III risks under the European Regulation 2016/425 under the conformity assessment procedure by the Notified Body Centexbel, with reference (XXXX). If XXXX = 2797, this means supervised product checks (Module D) by BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. If XXXX = 0493, this means supervised product checks (Module C2) by Centexbel Belgium (I.D. 0493), Technologiepark 7, B-9052 Zwijnaarde.
EAC TP TC 019/2011	Product is certified to the requirements of the Russian Custom Regulation TP TC 019/2011
	EN 420:2003 + A1:2009 = Prior to use, please read the Instructions
	EN388:2016 / A B C D E = Protection from mechanical risks: A: Abrasion resistance (performance levels 0 to 4) B: Blade cut resistance (performance levels 0 to 5) C: Tear resistance (performance levels 0 to 4) D: Puncture resistance (performance levels 0 to 4) E : TDM ISO EN 13997 cut resistance (performance levels A to F)
	EN ISO 374-5:2016 / VIRUS = Protection against bacteria, fungi and virus
	EN ISO 374-1:2016 / Type A, B or C / J K L O P S or T = Protection against chemical hazards: Type A = chemical breakthrough time > 30 minutes against at least 6 chemicals as per list defined in EN ISO 374-1:2016 Type B = chemical breakthrough time > 30 minutes against at least three chemicals as per list defined in EN ISO 374-1:2016 Type C = chemical breakthrough time > 10 minutes against at least one test chemical as per list defined in EN ISO 374-1:2016 (no code underneath the pictogram) J = n-heptane, K = sodium hydroxide, 40%, L = sulphuric acid, 96%, O = ammonia, 25%, P = hydrogen peroxide, 30%, S = hydrofluoric acid, 40%, T = formaldehyde, 37%
	EN 421:2010 = Protection against radio-active contamination
	Suitable for contact with foodstuffs. Compliant to the EU regulations 1935/2004 and 2023/2006

EU-Type examination certificate (Module B) by Centexbel Belgium (I.D. 0493), Technologiepark 7, B-9052 Zwijnaarde. **Warning!** Chemical resistance data has been assessed under laboratory conditions from samples taken from the palm only and relates only to the chemical tested. It can be different if it be used in a mixture. The data may not reflect the actual duration of protection in the workplace. Check that the gloves are suitable for the intended use. Conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation. When used, protective gloves may provide less resistance to the chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves. Chemical permeation data, tested per EN 16523-1:2015, and degradation data, tested per EN 374-4:2013, are available upon request. To obtain the EU-Conformity Declaration, please go to www.ansell.com/regulatory **B. Precautions for use: 1** Before use, inspect gloves for defects or imperfections such as holes, and tears. If the gloves are ripped or punctured during use, dispose of them immediately. If in doubt, do not use the gloves, get a new pair. **2** Contaminated gloves should be cleaned or washed before removals. **3** Ensure the chemicals cannot enter via the cuff. **4** Gloves shall not be used for protection against ionising radiation nor for use in containment enclosures. **5** The gloves should not come in contact with an open flame. **6** Not all gloves that are suitable for contact with foodstuffs may be used against all foodstuffs. Some gloves may show excessive migration towards certain types of foodstuffs. To know which restrictions apply and for which specific foodstuffs the gloves can be used, please obtain advice from Ansell or consult the Ansell Food Conformity declaration. **C. Ingredients / Hazardous ingredients:** Some gloves might contain ingredients which are known to be a possible cause of allergies in sensitised persons, who may develop irritant and/or allergic contact reactions. If allergic reactions should occur, obtain medical advice immediately. For more information, please contact Ansell **D. Care instructions - Storage:** Keep away from direct sunlight; store in a cool dry place and keep in the original packaging. Keep away from ozone sources. If gloves are properly stored, as indicated above, they won't lose their performances and won't change the glove characteristics significantly. If gloves could be affected by ageing or storage, the expiry date is mentioned on the packaging materials. **Cleaning:** The gloves are single-use and not designed to be laundered nor to be reused.


MICROTOUCH
Nitrile Powder-Free Medical Examination Gloves
M
7½-8
Ansell


M
7½-8
Nitrile
Powder-Free
Medical Examination Gloves
NITRILE
ACCELERATOR-FREE
MICROTOUCH
100
Ansell

EU DECLARATION OF CONFORMITY

The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM

declares under his sole responsibility, that the PPE described hereafter:

MICRO-TOUCH® Nitrile Accelerator-Free

Products manufactured as of: [30/10/2018] and till: [30/10/2023]

PPE to be used against category III risks

is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized standards EN 420:2003 + A1:2009, EN 421:2010, EN ISO 374-1:2016, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2018/1898, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 30/10/2018

EU DECLARATION OF CONFORMITY

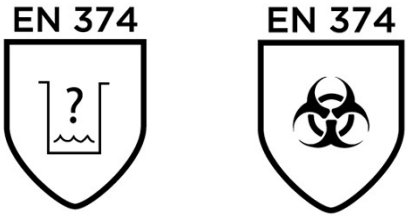
The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM

declares under his sole responsibility, that the PPE described hereafter:

MICRO-TOUCH® Nitrile Accelerator-Free

Products manufactured till: [29/10/2018]

PPE to be used against category III risks



is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized standards EN 374:2003, , EN 420:2003 + A1:2009 and is identical to the PPE which is subject to the EC Type examination; under certificate number 032/2015/0513 issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 23/04/2015

Permeation breakthrough times and degradation data according to EN ISO 374:2016

MICRO-TOUCH® Nitrile Accelerator-Free

	Chemical agent	CAS Number	Breakthrough Time (min)	Protection Index	Degradation (%)	Part
	Formaldehyde, 37%	50-00-0	> 480	6	48.8	Palm
	Sodium Hydroxide, 40%	1310-73-2	> 480	6	-0.3	Palm

Permeation breakthrough times according to EN ISO 374:2016						
0	1	2	3	4	5	6
< 10	10-30	30-60	60-120	120-240	240-480	> 480
Not recommended	Splash protection		Medium protection		High protection	

Data given in the table above are based on results of laboratory tests performed on the palm or cuff area of the glove. These tests were run using standard test methods that may not adequately replicate any specific conditions of end use. We wish to highlight that permeation times do not equate to safe wear time. Safe wear time may vary depending on whether the PPE is donned correctly, the surrounding temperature, the chemicals' toxicity, and other factors. Permeation information offered here is limited to the main protective material. Permeation times may vary around seams, zips, visors or any other joins or components of the PPE. It is the responsibility of your organization's Health and Safety professional to undertake a risk assessment before choosing the appropriate PPE for the task at hand. Because Ansell has no detailed knowledge or control over the conditions of end use, any of these data must be advisory only, and Ansell must decline any liability.

Ansell Healthcare Europe N.V.
Riverside Business Park, Block J
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http://www.ansell.eu E-mail info.europe@ansell.com

Ansell

VWR International bvba
Haasrode Researchpark 2020, Geldenaaksebaan 464, B-3001 Leuven
http://be.vwr.com

EU Declaration of Conformity

Manufacturer: [redacted].

Product Name	Item no.	UDI-DI	Intended Purpose
Classic Nitrile Examination gloves powder free blue and white colour, 100 pcs	290417-290421290411-290415	-	-Medical and Civil use (Protect patient and user from cross-contamination.)

The undersigned states that this declaration is issued under the sole responsibility of the manufacturer, Wei Sen Gloves Co.,Ltd., and that the object(s) of the declaration described in the table above are in conformity with the relevant Union harmonization legislation.
In the event of unauthorized modification of any of the products listed above, this declaration becomes invalid.

Object Name: [redacted]

Relevant EC Directives: PPE 2016/425/EU as last amended

Harmonized Standards: EN ISO 374-1:2016
EN ISO 374-5:2016
EN 420:2003+A1:2009

The notified body Satra Technology Europe Ltd, NB No 8278 performed the EU type-examination (module B) and issued the EU type-examination certificate 35205.2018.01

The PPE is subject to the conformity assessment procedure to type based on quality assurance of the production process (module D) under surveillance of the notified body Satra Technology Europe Ltd, NB No 8278.

Document number: 35205.2018.01

Place & date of issue: Leuven, 2019-05-07

Signed for and on behalf of VWR International bvba:

Kris Nijs
Managing Director

Certificate of Registration

nqa global assurance

Report of Conformity

Product:	Disposable PPE Gloves.
Type:	Nitrile Powder-Free Gloves & [redacted]
Applicant:	[redacted]
Addre	[redacted]

The submitted sample of the above product(s) have been tested for CE marking according to the related European Directives 93/42/EEC Medical Devices Directive (including 2007/47/EC)

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

Standard(s): EN ISO 14971:2009; EN 980:2008; EN 1041:2008; EN ISO 10993-1:2009; EN ISO 10993-5:2009; EN ISO 10993-10:2009

The technical documentation of the listed devices is in conformity with the requirements.
The test report is the annex of this report and we suggested they could be used together.
The applicant may affix the CE marking as shown below to the product.

Report No.: 01933
Date: 10 June 2018
Expiry Date: 09 June 2023

General Manager (Signature)

CE

EC Certificate
Full Quality Assurance System

Certificate No.: **239534-2017-CE-TH-NA-PS**

Project No.: **PRJC-535567-2015-MSL-TH**

Valid Until: **06 September 2022**

This is to certify that the quality system of:

[redacted]

For design, production and final product inspection/testing of:

Disposable Medical Devices

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 09 September 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus

Tone Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
239534-2017-CE-TH-NA-PS	**PRJC-535567-2015-MSL-TH**	**06 September 2022**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original certificate	2017-09-06

Products covered by this Certificate:

Product Description	Product Name	Class
Surgical Rubber Gloves and Specialty Gloves	Surgical latex gloves - sterile & non-sterile (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves) Elbowlength gynaecology procedure latex gloves - sterile & non-sterile (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves) Double pair speciality gloves (high risk gloves) - sterile (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves) Orthopaedic speciality gloves - sterile (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves) Micro surgery speciality gloves - sterile (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves) Ultra Nulife sterile surgical gloves (beadless & beaded gloves) (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves)	IIa
Examination Latex Gloves	Sterile & non-sterile (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves)	Is
Examination Latex-free Gloves	Sterile & non-sterile (Powdered Gloves, Powder Free Chlorinated Gloves, Powder Free Polymer Coating Gloves)	Is

Non-active devices for emergency & intensive care	Penrose Drainage Tubing	IIa
Non-active devices for emergency & intensive care	Male Incontinence device (U-Drain)	Is

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

[redacted]

EU Representative

Obelis s.a, 34, Av de Tervuren, Bte 44, B-1040 Brussels, BELGIUM

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
239534-2017-CE-TH-NA-PS	**PRJC-535567-2015-MSL-TH**	**06 September 2022**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

[redacted]

REF 905752 (as of LOT 131793)

Product Description and Purpose

[redacted]owder-free medical examination gloves and protective gloves, **size M (8).** They are made of nitrile rubber. The nonsterile, **blue-purple** disposable gloves are ambidextrous. They are used for medical examinations, for diagnostic and therapeutic purposes, for the handling of contaminated medical materials, for protection against cross-contaminations, but also for the handling of chemicals, in medicine, health care, or laboratories. They are approved for food contact.

Contra-Indications

No contra-indications known.

The product must not be used if there is a known allergy to one of the below mentioned ingredients.

Composition

Nitrile rubber (NBR)
The product contains dithiocarbamates.
The product is latex-free.

Normative and Legal Requirements

soft with double function are on the one hand medical devices according to MPG (Medical Devices Act), Directive 93/42/EEC and Regulation MDR (EU) 2017/745 and are classified as class I, rule 5 products, and on the other hand they are protective gloves according to the PPE Regulation (EU) 2016/425 category III.

They comply with the requirements of EN 455 part 1, 2, 3 and 4 and EN 420, EN 374 part 1, 2, 4 and 5.

Suitable for food according to EN 1186.

The AQL is ≤ 1,5 referring to the imperviousness, in compliance with EN 455-1.

The powder content of all gloves is below the maximum permissible normative value of 2 mg/ glove (EN 455-3).

The biocompatibility is tested acc. to DIN EN ISO 10993 and the protection against microorganisms (viruses, bacteria and fungi) acc. to EN 374-5.

The product does not contain dangerous toxic substances according to REACH.

All packing levels are labelled acc. to DIN EN ISO 15223-1 and EN 1041.

CE 2777, PPE Regulation (CAT III), SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Ireland

Packaging

Primary packaging:	folding box made ot cellulose
Secondary packaging:	carton made of cellulose

Storage

To be stored in a dry and dust-free environment between +5°C and +40°C, protected from direct solar radiation

The product bears the following symbols and marking

CE 2777

Medical device class I
EN 455-1: 2000; EN 455-2:2015;
EN 455-3: 2015; EN 455-4: 2009

PPE (CAT III)
EN 420: 2003+A1:2009

EN 374-1: 2016: 2016+ A1:2018

Permeation levels are based on breakthrough times as follows:						
Level	1	2	3	4	5	6
Min breakthrough times (min)	>10	>30	>60	>120	>240	>480

EN ISO 374-1: 2016 Type B

Test according to EN 16523-1:2015 The penetration resistance has been assessed under laboratory condition and relates only to the tested specimen	EN ISO 374-1: 2016/ Type B KPT	Sodium hydroxide (K) 40 % Level 6 Hydrogen peroxide (P) 30 % Level 2 Formaldehyde (T) 37 % Level 5

374-4: 2013

Chemical	CAS No	Degradation
Sodium hydroxide (K) 40%	1310-73-2	-25.7 %
Hydrogen peroxide (P) 30%	7722-84-1	44.8 %
Formaldehyde (T) 37%	50-00-0	-17.1 %

The degradation level indicates the value from which the effect of the degradation (modification of glove material) through the tested chemical is verifiable.

EN 374-5: 2016:

EN ISO 374-5: 2016	Level	EN ISO 374-5: 2016
Protection against bacteria and fungi	Pass	VIRUS
Protection against virus	Pass	Level 2, AQL ≤ 1.5

374-2: 2014

Performance Level	AQL	Inspection levels
Level 3	<0.65	G1
Level 2	<1.5	G1
Level 1	<4.0	S4

Note
Depending on working conditions, the actual duration of protection may deviate from the values in the tables.

Check for damage before use. Do not use damaged gloves.

No reprocessing.

Waste disposal in accordance with current regulations.

Date of information: 01.12.2019 [REV 12], 2 pages
replaced: 14.08.2017 [Rev 11], 2 pages

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

[redacted]

Holds Certificate No: **MD 600017**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The manufacture of powder-free latex examination gloves and powder-free nitrile examination gloves.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-03-06 Effective Date: 2020-03-06

Latest Revision Date: 2020-02-21 Expiry Date: 2023-03-05

...making excellence a habit.™

[redacted]

SUBJECT: REAL TIME SHELF LIFE STUDY REPORT – POWDER FREE NITRILE EXAMINATION GLOVES

Date: 5th of April, 2019.

Objective : To perform Real Time Shelf Life Study according to EN 455–Part 4: Requirements and Testing for Shelf Life Determination Standard to determine the shelf life of the Powder Free Nitrile Examination Gloves.

Method : Packed Powder Free Nitrile Examination Gloves were conditioned at 25° ± 2° C for the intended shelf life period and samples are then tested at pre-determined intervals for Force at Break Before Accelerated Aging according to EN 455–Part 2: Requirements & Testing for Physical Properties Standard and for Watertightness according to EN 455–Part 1: Requirements & Testing for Freedom From Holes.

Samples were taken from the following batches:

Lot	Batch No.	Gloves Size	Lot Size	Date of Test
Lot A	4124115B1	S	12,000 pcs	1st of April, 2014 – 1st of April, 2019
Lot B	4124113A2	M	12,000 pcs	1st of April, 2014 – 1st of April, 2019
Lot C	4124112B2	L	12,000 pcs	1st of April, 2014 - 1st of April, 2019

The sample were stored under ambient conditions of (25° ± 2°C) and relative humidity of (50 ± 5%) for a specified period (5 years). Every 6 months, 13 pieces were removed from the lot sample and tested as per requirements of EN 455–Part 2: Requirements & Testing for Physical Properties Standard. Also, another 32 pieces were removed from the lot sample and tested as per requirements of EN 455–Part 1: Requirements & Testing for Freedom From Holes Standard. After 5 years, the results obtained are as following:

Results:

Part A: Force at Break Before Accelerated Aging

Specification: Force at Break = 6.0 N (Median)

Sample Size: 13 pieces

Date Of Sampling	Median Force at Break (N)	Average Sample Thickness (mm)
1st of April, 2014 (Initial)	7.26	0.101
1st of October, 2014	7.65	0.102
1st of April, 2015	7.73	0.097

[redacted]

[redacted]

1st of October, 2015	8.12	0.097
1st of April, 2016	8.16	0.102
1st of October, 2016	7.93	0.101
1st of April, 2017	7.49	0.098
1st of October, 2017	7.33	0.102
1st of April, 2018	7.18	0.102
1st of October, 2018	7.03	0.104
1st of April, 2019	6.84	0.101

Observation / Comment: The force at break for each interval increased in a small fraction over the first two years of storage period and started to decline slowly from the second year till end of the storage period of 5 years. The result shows that the powder free nitrile examination gloves complies to the requirement of EN 455–Part 2: Requirements & Testing for Physical Properties Standard over the 5 years study period.

Part B: Watertightness

Maximum Permitted Defective: AQL 1.5 ; G1 (Accept: 1 piece, Reject: 2 pieces)

Sample Size: 32 pieces

Date Of Sampling	Defect Found (pieces)
1st of April, 2014 (Initial)	0
1st of October, 2014	0
1st of April, 2015	0

[redacted]

1st of October, 2015	0
1st of April, 2016	1
1st of October, 2016	0
1st of April, 2017	0
1st of October, 2017	0
1st of April, 2018	1
1st of October, 2018	0
1st of April, 2019	0

Observation / Comment: The samples tested meet the requirement of EN 455–Part 1: Requirements & Testing for Freedom From Holes Standard over the 5 years study period.

Discussion & Conclusion:

EN 455–Part 4: Requirements and Testing for Shelf Life Determination Standard is an harmonised standard for the requirement and testing for shelf life determination of medical gloves for single use. The standard requires manufacturer to test the properties of the glove that can alter during natural aging (shelf life of the product). The properties that require testing shall include, but are not limited to; Force at Break (EN 455-Part 2) and Freedom from Holes (EN 455-Part 1).

The result above showed that our Powder Free Nitrile Examination Gloves are complied to the requirement of EN 455–Part 2: & EN 455–Part 1 over the 5 years study period, thus the gloves are claimed to have a shelf life of 5 years based on the Real Time Shelf Life Study test results above which conform to EN 455 – Part 4 standard.

Reported By:

[redacted]

Verified By:

DuangChan
WSG Manager

[redacted]