

# SAFETY MANAGED

Reduced Injuries by 65%



## WHY ANSELL

As a global leader in protection solutions, we design, develop and manufacture a wide range of protection solutions that meet the ever-changing needs of our markets. Our vision is to create a world where people can enjoy optimal protection against the risk they are exposed to. And, with offices and plants across 55 countries, we are looking for individuals who are ready to make an impact and help us create a safer, "Ansell protected" world. We empower and challenge our diverse community of employees to create innovative solutions that will protect millions of people around the world. If you are looking for an opportunity that makes a difference, give Ansell a look.

**10**  
billion

Manufacturing more than 10 billion gloves per year

**10**  
million

Protecting more than 10 million workers each day

**10**  
billion

Manufacturing more than 10 billion gloves per year

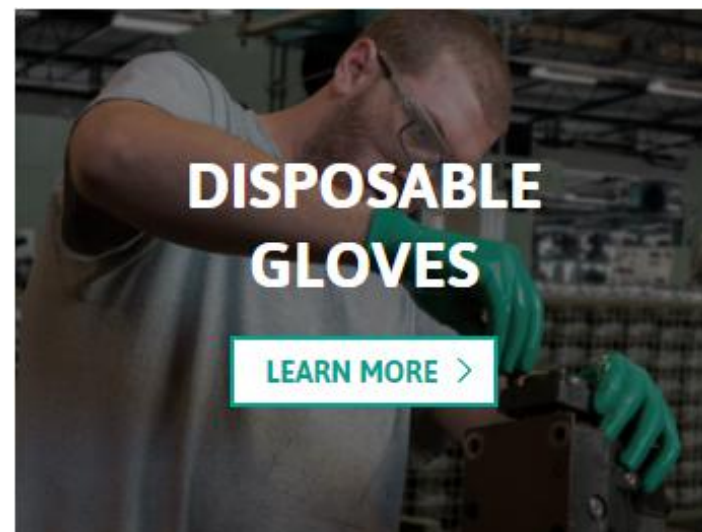
**25**  
industries

Providing protection solutions to more than 25 specific industries

**100**  
countries

Sales activities in more than 100 countries

# INDUSTRIAL PRODUCTS



# BROWSE PRODUCTS

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## INDUSTRIAL HAND AND ARM PROTECTION

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Chemical & Liquid Protection

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Mechanical Gloves & Sleeves

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Disposable Gloves

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## BODY PROTECTION

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Gas & Vapor

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Liquid Spray & Splash

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Particulate or Low Hazard

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Ventilated/Air Fed

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Chemical Flame Retardant

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Diving

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## HEALTHCARE

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Surgical Gloves

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Exam Gloves

---

Specialty Gloves

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Safety Devices

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## LIFE SCIENCES

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Gloves

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Protective Clothing

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Goggles

---

RABS and Isolator Gloves

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Face Masks

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Accessories

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## HEALTHCARE PRODUCTS



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## BRANDS

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## MICRO-TOUCH®



MICRO-TOUCH® Nitrile



MICRO-TOUCH® Micro-Thin™ Nitrile



MICRO-TOUCH® Royal Blue Nitrile



MICRO-TOUCH® NITRAFREE™ Blue



MICRO-TOUCH® Nitrile E.P.



MICRO-TOUCH® Nitrile Sterile



MICRO-TOUCH® Nitrile Sterile Singles



MICRO-TOUCH® DENTA-GLOVE® Blue Nitrile



MICRO-TOUCH® Central Supply – SPD Plus ULNCS

## ① MICRO-TOUCH®



MICRO-TOUCH® Micro-Thin™ Nitrile

### STANDARDS AND CERTIFICATIONS

ASTM D6319


Category III; EN 420:2003 + A1:2009

EN 455 1-4; EN 455 1-4



FDA21 CFR 177-2600



ISO 10993-10:2002; 

 ISO 13485



**Ansell**

**MICRO-TOUCH<sup>®</sup>**



## **MICRO-TOUCH<sup>®</sup> Micro-Thin<sup>™</sup> Nitrile**

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**Nitrile, powder-free examination glove with a thin film formulation for unrestricted tactile sensitivity**

### **KEY FEATURES AND BENEFITS**

**Excellent tactile sensitivity is ideal for palpating veins and starting IVs**

**The textured surface of the glove promotes sure handling of materials and instruments**

**300 gloves per box reduces restocking and reorders**



## PRODUCT CATEGORY

Medical Exam Gloves

### MICRO-TOUCH<sup>®</sup> Micro-Thin<sup>™</sup> Nitrile

#### DESCRIPTION

This non-sterile glove is made with a thinner formulation to provide excellent tactile sensitivity and dexterity along with exceptional comfort, fit and feel. High quality manufacturing ensures this glove will hold up for a variety of clinical procedures.

#### KEY FEATURES AND BENEFITS:

- Excellent tactile sensitivity is ideal for palpating veins and starting IVs
- The textured surface of the glove promotes sure handling of materials and instruments
- 300 gloves per box reduces restocking and reorders

#### PRIMARY INDUSTRIES

- Healthcare

#### PACKAGING

SIZE	CODE	PACKAGING
XS (5.5 - 6)	6034310	300 gloves per dispenser 10 dispensers per case 3000 gloves per case
S (6.5 - 7)	6034311	
M (7.5 - 8)	6034312	
L (8.5 - 9)	6034313	
XL (9.5 - 10)	6034314	

# Ansell

# MICRO-TOUCH<sup>®</sup>

## PRODUCT CATEGORY

### Medical Exam Gloves



**MICRO-TOUCH<sup>®</sup> Micro-Thin<sup>™</sup>**  
**Nitrile**

#### RECOMMENDED FOR

- Enhanced tactile sensitivity and dexterity, especially for delicate procedures
- Protection from Type I latex allergy in HCW's or patients
- Brief, low-risk examination procedures
- Environmentally friendly facilities

#### PRODUCT DETAILS

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)	0.06 / 2.4
FINGER THICKNESS (MM/MIL)	0.09 / 3.5
ALLERGY PREVENTION	LATEX (TYPE I)
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 AND US FDA CLEARED
STERILE	NO
ANTISTATIC	NOT TESTED
GLOVE LENGTH (MM/INCHES)	230 / 9.1
PRODUCT SEGMENTATION	ESSENTIAL SERIES

## Product Data Sheet

### MICRO-TOUCH® Micro-Thin™ Nitrile

Essential Series

#### Nitrile, powder-free examination glove with a thin film formulation for unrestricted tactile sensitivity

This non-sterile glove is made with a thinner formulation to provide excellent tactile sensitivity and dexterity along with exceptional comfort, fit and feel. High quality manufacturing ensures this glove will hold up for a variety of clinical procedures.

##### KEY FEATURES AND BENEFITS:

- Excellent tactile sensitivity is ideal for palpating veins and starting IVs
- The textured surface of the glove promotes sure handling of materials and instruments
- 300 gloves per box reduces restocking and reorders

##### Recommended For

- Enhanced tactile sensitivity and dexterity, especially for delicate procedures
- Protection from Type I latex allergy in HCW's or patients
- Brief, low-risk examination procedures
- Environmentally friendly facilities

##### 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® Micro-Thin™ Nitrile

Essential Series

#### 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)	0.06 / 2.4
Finger Thickness (mm/mil)	0.09 / 3.5	Allergy Prevention	Latex (Type I)
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 and US FDA cleared
Sterile	No	Antistatic	Not Tested
Glove Length (mm/inches)	230 / 9.1	Product Segmentation	Essential Series

#### 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	6034310	6034311	6034312	6034313	6034314

#### PACKAGING AND STORAGE

Packaging	300 gloves per dispenser 10 dispensers per case 3000 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

ASTM D6319, Category III, EN 420:2003 + A1:2009, EN 455 1-4, EN 455 1-4, EN ISO 374-1:2016, EN ISO 374-5:2016, FDA21 CFR 177-2600, ISO 10993-10:2002, ISO 9001, ISO 13485

## 510(k) Premarket Notification

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FDA510K  
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Notificator

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<b>Device Classification Name</b>	<a href="#">Polymer Patient Examination Glove</a>
<b>510(K) Number</b>	K200671
<b>Device Name</b>	Microflex Nitrile Patient Examination Gloves With Aloe And Chamomile Blue Green Pink Colored Tested For
<b>Applicant</b>	Ansell Healthcare Products LLC 2301 Robb Drive Reno, NV 89523
<b>Applicant Contact</b>	Donald Cronk
<b>Correspondent</b>	Ansell Healthcare Products LLC 2301 Robb Drive Reno, NV 89523
<b>Correspondent Contact</b>	Donald Cronk
<b>Regulation Number</b>	<a href="#">880.6250</a>
<b>Classification Product Code</b>	<a href="#">LZA</a>
<b>Subsequent Product Codes</b>	<a href="#">LZC</a> <a href="#">QDO</a>
<b>Date Received</b>	03/13/2020
<b>Decision Date</b>	06/19/2020
<b>Decision</b>	Substantially Equivalent (SESE)
<b>Regulation Medical Specialty</b>	General Hospital
<b>510k Review Panel</b>	General Hospital
<b>Summary</b>	<a href="#">Summary</a>
<b>Type</b>	Traditional
<b>Reviewed By Third Party</b>	No
<b>Combination Product</b>	No

## Establishment Registration & Device Listing

[FDA Home](#) [Medical Devices](#) [Databases](#)



1 to 2 of 2 Results for **Establishment Registration or Business Trade Name :**  
Ansell Healthcare Products

Results per Page  [New Search](#)

Establishment Name	Registration Number	Current Registration Yr
<a href="#">ANSELL HEALTHCARE PRODUCTS LLC</a> NJ/USA	3009964047	2021
<ul style="list-style-type: none"> <li><a href="#">Polymer Patient Examination Glove - MICROFLEX N64X ONYX</a></li> <li><a href="#">Polymer Patient Examination Glove - Micro-Touch Micro-Thin 431: STRETCHLEASE G416X</a></li> <li><a href="#">Polymer Patient Examination Glove - UltraSense (INTL): UltraSense EC PF Nitrile Exam; UltraSense PF Nitrile Exam; UltraSense Plus (INTL)</a></li> <li><a href="#">Polymer Patient Examination Glove - UltraSense EC</a></li> </ul>		Specification Developer Specification Developer Manufacturer; Specification Developer Manufacturer; Specification Developer
<a href="#">ANSELL HEALTHCARE PRODUCTS LLC</a> NV/USA	3011209798	2021
<ul style="list-style-type: none"> <li><a href="#">Polymer Patient Examination Glove - Fisherbrand EC Nitrile; Integra; Long Cuff Nitrile; PF Nitrile Glove</a></li> <li><a href="#">Polymer Patient Examination Glove - PF Nitrile Glove; Softwear Nitrile Exam</a></li> <li><a href="#">Latex Patient Examination Glove - Micro One LP Latex Exam; PowerGrip LP Latex Exam</a></li> <li><a href="#">Patient Examination Glove, Specialty - Sensation</a></li> <li><a href="#">Polymer Patient Examination Glove - MidKnight PF Nitrile Exam</a></li> </ul>		Manufacturer; Specification Developer Manufacturer; Specification Developer Manufacturer; Specification Developer Manufacturer; Specification Developer Manufacturer; Specification Developer
<ul style="list-style-type: none"> <li><a href="#">Show all 99 Listings For ANSELL HEALTHCARE PRODUCTS LLC NV/USA</a></li> </ul>		

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FDA  
certificate  
of product  
registration

## SGS

**Test Report** No.: SHHL1703010719MD5 Date: MAR. 28. 2020 Page: 1 of 5

THE TEST REPORT IS TO SUPERSEDE THE TEST REPORT No..SHHL1703010719MD5  
DATE: MAR. 22, 2020

The following sample(s) was/were submitted and identified by the client as:

Sample Description : BLUE NITRILE EXAMINATION GLOVES  
SGS Ref. No. : ODHL17030042090  
LOT No. : 5516-20170107  
Sample Receiving Date : MAR. 13. 2020  
Testing Period : MAR. 13. 2020 TO MAR. 22. 2020  
Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT  
Test Requested : 1. FREEDOM FROM HOLES (ASTM D6319-10 CLAUSE 6.1.2)

2. PHYSICAL DIMENSIONS (ASTM D6319-10 CLAUSE 6.1.3)


3. PHYSICAL PROPERTY CHARACTERISTICS (ASTM D6319-10 CLAUSE 6.1.4)

4. POWDER RESIDUE FOR POWDER FREE GLOVES (ASTM D6319-10 CLAUSE 6.1.5)

Test Result(s) : FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S)

Conclusion : THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT

Signed for and on behalf of  
SGS (Thailand) Limited

  
Usaporn Kaewmanee  
Laboratory Co-ordinator

USGS2 This Test Report is issued by the Company subject to its General Conditions of Service printed overleaf. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues defined therein. The results shown in this test report refer only to the sample(s) tested unless otherwise stated. This Test Report cannot be reproduced, except in full, without prior written permission of the company.

## SGS

**Test Report** No.: SHHL1703010719MD5 Date: MAR. 28. 2020 Page: 2 of 5

### Test Conducted:


ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application

Number of test sample : 244 pcs  
Accelerated aging condition : 70 °C, 166 h  
Defects observed before testing : No defect  
Test Result : Pass

Clause	Test Items	Result	Note
6.1.2	Freedom from Holes	Pass	#1
6.1.3	Physical dimensions	Pass	#2
6.1.4	Physical Property characteristics	Pass	#3
6.1.5	Powder Residue For Powder Free Gloves	Pass	#4

Notes : # 1- Test details see test result 1.  
# 2- Test details see test result 2.  
# 3- Test details see test result 3.  
# 4- Test details see test result 4.  
# 5- The sample selecting amount for Freedom from Holes is deviated to 200 pcs as assessed by SGS.  
# 6- The sample selecting amount for Physical dimensions and Physical property characteristics is deviated to 13 pcs per test as assessed by SGS.  
# 7- The hardness of the glove is materials < 35 IRHD as per client's claim.

Signed for and on behalf of  
SGS (Thailand) Limited

  
Usaporn Kaewmanee  
Laboratory Co-ordinator

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## SGS

**Test Report** No.: SHHL1703010719MD5 Date: MAR. 28. 2020 Page: 3 of 5

**Test Result:**

**1. Freedom from Holes**

Sample Quantity: 200

AQL: 2.5 Accept: 10 Reject: 11 Found: 0

**2. Dimensions**

Sample Quantity: 13

AQL: 4.0 Accept: 1 Reject: 2 Found 0

Size	Sample No.	Length mm	Width mm	Thickness at finger mm	Thickness at palm mm
M	1	245	95	0.094	0.058
	2	246	95	0.099	0.062
	3	235	95	0.103	0.059
	4	243	95	0.096	0.058
	5	240	95	0.106	0.062
	6	242	95	0.093	0.060
	7	245	98	0.103	0.061
	8	246	96	0.094	0.058
	9	245	95	0.100	0.059
	10	243	94	0.093	0.056
	11	243	95	0.086	0.056
	12	245	94	0.089	0.063
	13	243	95	0.091	0.060
Found	0	0	0	0	

Requirements: see table 1

**Table 1 Dimensions and tolerances**

NOTE: Sizing that falls within the tolerance overlaps between two sizes may be labeled as a size range including both sizes. For example, small medium and medium large.

Designation	Size						Tolerance, mm
	6	6½	7	7½	8	8½	
Width by size, mm	75	83	89	95	102	105	±6
Width by		x-small	small	unsize	medium	large	X-Large
Length, mm		70	80	85	95	110	120
Thickness, mm		220	220	230	230	230	±10
Finger				0.05			Min.
Palm				0.05			Min.

Signed for and on behalf of  
SGS (Thailand) Limited

Usaporn Kaowmanee  
Laboratory Co-ordinator

## SGS

**Test Report** No.: SHHL1703010719MD5 Date: MAR. 28. 2020 Page: 4 of 5

**3. Tensile Properties**

Sample Quantity: 26

AQL: 4.0 Accept: 1 Reject: 2 Found 0

Sample No.	Before ageing		After ageing	
	Tensile strength MPa	Ultimate Elongation %	Tensile strength MPa	Ultimate Elongation %
1	21.6	856.7	27.3	793.3
2	31.3	746.7	31.6	833.3
3	34.6	749.6	23.2	708.7
4	31.7	1023.3	32.2	893.3
5	29.3	996.7	24.8	880.0
6	23.3	916.7	29.9	810.0
7	21.9	952.5	28.1	806.7
8	30.4	1016.7	29.5	806.7
9	29.5	1040.0	32.7	856.7
10	34.1	1058.8	34.3	1023.3
11	28.3	1030.0	30.1	853.3
12	17.1	826.7	26.1	846.7
13	25.5	976.6	32.3	980.0
Found	0	0	0	0

Requirements: see table 1

**Table 1- Physical requirements**

Before aging		After aging	
Tensile strength	Ultimate Elongation	Tensile strength	Ultimate Elongation
14 MPa Min.	500% Min.	14 MPa Min.	400% Min.

**4. Powder Residue for Powder Free Gloves**

Test Item	Test Method	Requirement	Test result	Rating
Powder residue	Clause 7.6	Have a powder residue limit of 2.0 mg.	0.46	Pass

Signed for and on behalf of  
SGS (Thailand) Limited

Usaporn Kaowmanee  
Laboratory Co-ordinator

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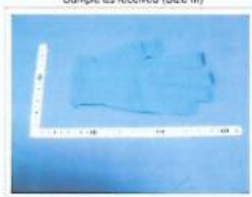
## SGS

### Test Report

No.: SHHL1703010719VDS    Date: MAR. 28, 2020    Page: 5 of 5

Sample Photo:

Sample as received (Size M)



SGS authenticate the photo on original report only

\*\*\*End of Report\*\*\*

Signed for and on behalf of  
SGS (Thailand) Limited

  
Usaporn Kaewmanee  
Laboratory Co-ordinator

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## Certificate of freesale



สำนักงานคณะกรรมการอาหารและยา  
Food and Drug Administration

CERTIFICATE OF FREE SALE

Ref.No. 2-1-20-02-20-01102

February 27, 2020

It is hereby certified that

does manufacture medical in Thailand pursuant to the Medical Devices Act 2008.

The following product may be sold in Thailand and exported without restriction.

Name of Product : Examination Gloves, Nitrile Examination Glove, Disposable Vinyl Gloves, Face Mask

This certificate is issued upon the request of Phangan Company Limited

Valid until 26 February 2023

(Mrs. Sittaya Sumanant)  
Pharmacist, Professional Level  
Person designated by the Secretary-General  
of the Food and Drug Administration

ISO9001

## Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 10 149 064910

TÜV Rheinland Cert GmbH certifies:

Certificate Holder:

Scope: **Manufacturing of Latex Concentrate, Mask Crepe, Non Sterile Medical Gloves and Non Sterile and Sterile Surgical Gloves**

An audit was performed, Report No. 064959. Proof has been furnished that the requirements according to ISO 9001 :2015 are fulfilled.  
The due date for all future audits is 26-12 (dd.mm).

Validity: The certificate is valid from 2020-01-30 until 2022-12-27. First certification 2006

2020-01-30



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln



DGA-ZM-58-95-00

## CE certificate

International Certification Registrar



### PPE REGULATION (EU) 2016/425 MODULE C2 CERTIFICATE

Name and address of  
Certificate owner:

EU type Examination

Certificate Number: 2877/11804-02/E00.00

Product Group Reference: 697024575

Blue 697024575 601-605  
Violet 69724575 631-635  
White 69724575 641-645  
Black 69724575 651-655

Product type: Disposable nitrile Non-sterile gloves

Classification: EN ISO 374-1:2016+A 1:2018 Type B

This is to certify that the following products tested above reports referenced: STE0293607 & CHMO295494/2009/JH have found to satisfy the requirement of PPE regulation (EU) 2015/425 module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe

EN ISO 374-1:2016+A 1:2018 Type B

No. of test reports: 1.20.02.69

Certificate issue date: 6<sup>th</sup> March 2020

Expiration date: 5<sup>th</sup> March 2023

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.  
SATRA Technology Europe Limited, Bracktown Business Park, Clonsilla, Dublin 15, D15 Y6Z7, Republic of Ireland  
(Notified Body Number 2777)  
Tel: +353 (0) 1 437 2484 Web: [www.satratouch.com](http://www.satratouch.com)



# EU DECLARATION OF CONFORMITY

## 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<sup>®</sup> Micro-Thin<sup>™</sup> Nitrile**

*Products manufactured till: [21/01/2024]*

**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 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 032/2019/0118, 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

A handwritten signature in black ink, appearing to read 'Guido Van Duren'.

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 21/01/2019



