



SensiCare® Silk

EN 455-1 AQL 1.0

M



NITRILE

POWDER-FREE
NITRILE EXAM GLOVES

200 

3 PPE
PERSONAL
PROTECTIVE
EQUIPMENT
CATEGORY

Personal Protective Equipment of Complex Design Category III, in compliance with Regulation (EU) 2016/425, type tested to EN420:2003+A1:2009, EN ISO 374-1:2016, EN374-2:2014, EN 16525-1:2015, EN374-4:2013, ISO15804:2004, EN ISO 374-5:2016 & ASTM D6976 Class I Medical Device, in compliance with Regulation 2017/745, type tested to EN 455-1:2000, EN 455-2:2009, EN 455-3:2006, EN 455-4:2009

Approved for use with some chemotherapy drugs per ASTM D6976. Please contact Medline for detailed information.



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NITRILE EXAM GLOVES

CE

Medical Device class I under Regulation 2017/745 0086 (Personal Protective Equipment category III under Regulation (EU) 2016/425) BSI, MK5 8 PP, UK

M

REF MDS9085



SensiCare® Silk

M

POWDER-FREE
NITRILE EXAM GLOVES

- en Latex-free, powder-free nitrile examination gloves, single use only, non-sterile.
- de Latexfreie, puderrfreie Nitril-Einweg-Untersuchungshandschuhe, nicht steril.
- fr Gants d'examen en nitrile sans poudre, sans latex, à usage unique, non stérile.
- nl Latexvrije, poedervrije, nitril handschoenen, eenmalig gebruik, niet-steriel.
- it Guanti monouso in nitrile per esplorazione, senza polvere e senza lattice, non sterili.
- es Guantes de examen de nitrilo sin polvo, sin látex, de un solo uso, no esterilizados.
- pt Luvas de nitrila para exame, sem látex, sem pó, de uso único, não esterilizadas.
- sv Nitril undersökningshandskar, puderrfria och latexfria, för engångsbruk, osterila.
- fi Lateksittomat, sisältä puuterittomat, nitrilivalmistetut tutkimuskäsineet, kertakäyttöiset, ei sterilöidyt.
- da Latexfri, puderrfri nitril undersøgelsehandsker, engangsbrug, usteril.
- pl Jednorazowe, niesyrytne, Nie zawiera lateksu, bezpudrowe nitylowe rękawiczki do badania z przedzielnym naklejem.



POWDER-FREE
NITRILE EXAM GLOVES | 200

EN455

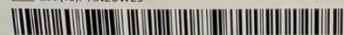
	XS	REF MDS9083	Extra-Small, Extra-klein, XS, Extra small (XS), Extra piccoli, Extra pequeño, Extra-pequeno, Extra small, XS, Ekstra Small, Ekstra Male
	S	REF MDS9084	Small, Klein, S, Small (S), Piccoli, Pequeño, Pequeno, Small, S, Small, Male
	M	REF MDS9085	Medium, Mittel, M, Medium (M), Medi, Mediano, Medio, Medium, M, Medium, Medium
	L	REF MDS9086	Large, Groß, L, Large (L), Grandi, Grande, Grande, Large, L, Large, Stor
	XL	REF MDS9087	Extra-Large, Extra-groß, XL, Extra large (XL), Extra grandi, Extra grande, Extra-grande, Extra large, XL, Ekstra Large, Ekstra store

2 00531 28 0535

GTIN (01): 3088827760658

Exp (17): 2023-05-28 Date of Mfg: 2020-06-01

LOT Lot (10): AN20W25



(01)3088827760658(17)230528(10)AN20W25

- en **Storage and transport recommendation:** Protect from freezing, avoid excessive heat. Shield from direct sunlight, fluorescent lighting, x-rays, moisture and ozone. Check for damage before use. Do not use damaged gloves. Contains dithiocarbamates, do not use in case of hypersensitivity. **Disposal:** Dispose of in accordance with local regulations.
- de **Lagerungs- und Transportempfehlung:** Bei Raumtemperatur lagern, übermäßige Hitze vermeiden. Vor direkter Sonneneinstrahlung, Neonbeleuchtung, Röntgenstrahlen, Feuchtigkeit und Ozon schützen. Bitte überprüfen Sie die Ware vor Gebrauch auf Beschädigungen. Bitte Die Entsorgung hat nach
- fr **Recommandations de stockage et de transport :** Tenir à l'écart du gel et de la chaleur excessive. Protéger d'un ensoleillement direct d'un éclairage aux néons, des rayons X, de l'humidité et de l'ozone. Vérifier l'état des gants avant usage. Ne pas utiliser de gants endommagés. Contient des dithiocarbamates, ne pas utiliser en cas d'hypersensibilité à cet agent de vulcanisation. **Élimination:** Éliminer conformément à la législation locale.
- nl **Opslag en transport advies:** Beschermen tegen bevriezing, overmatige hitte vermijden. Afslermen tegen direct zonlicht, fluorescerende verlichting, röntgenstralen, vocht en ozon. Controleer op beschadigingen vóór gebruik. Gebruik geen beschadigde handschoenen. Bevat dithiocarbamaten, niet te gebruiken in geval van overgevoeligheid. **Verwijdering:** Verwijderen in overeenstemming met de lokale regelgeving.
- it **Istruzioni per stoccaggio e trasporto:** Proteggere da fonti elevate di calore o freddo, mantenere in luogo asciutto e pulito. Il prodotto va conservato lontano da luce diretta del sole, fonti di RX, fonti fluorescenti, umidità ed ozono. Verificare eventuali danni prima dell'uso. Non utilizzare quando danneggiati. Contiene ditiocarbammati, non usare in caso di ipersensibilità. **Eliminazione:** Eliminare secondo le regolamentazioni locali.
- es **Recomendaciones de almacenamiento y transporte:** Proteja de la congelación, evite el calor excesivo. Proteja de la luz solar directa, iluminación fluorescente, rayos X, humedad y ozono. Revísar si hay daños antes de su uso. No utilizar guantes dañados. Contiene Ditiocarbamatos, no utilizar en caso de hipersensibilidad. **Desecho:** Desechar de acuerdo con los reglamentos locales.
- pt **Recomendações de armazenamento e transporte:** Proteger do frio ou calor excessivo. Resguardar da luz solar direta, luz fluorescente, raios X, humidade e ozono. Revistar se está danificado antes do uso. Não utilizar luvas danificadas. Contém ditiocarbamatos, não utilizar em caso de hipersensibilidade. **Descarte:** Descartar de acordo com os regulamentos locais.
- sv **Förvarings och transport rekommendationer:** Skydda mot frost, undvik överdriven värme. Skydda från direkt solljus, lysrör, röntgen, fukt och ozon. Kontrollera eventuella skador före användning. Använd ej skadade handskar. Innehåller ditiocarbamat, använd ej vid överkänslighet. **Bortskaffande:** Kasta bort enligt med lokal lagstiftning.
- fi **Säilytys- ja kuljetusohjeet:** Suojattava jäätymiseltä, vältettävä liiallista kuumuutta. Suojattava suorasta auringonvalolta, UV-valosta, röntgenvalosta, kosteudelta ja oksygeniltä. Tarkista vaurioiden varalta ennen käyttöä. Älä käytä vaurioituneita käsineitä. Sisältää ditiokarbamaattia, älä käytä, jos olet yliherkkä. **Ääritäminen:** Heittää paikallisten sääntöjen mukaan.
- da **Opbevarings- og transport anbefalinger:** Beskyt mod frost, undgå for meget varme. Beskyt mod direkte sollys, fluorescerende lys, røntgen, fugt og ozon. Check for beskadigelse før brug. Brug ikke beskadigede handsker. Indeholder ditiocarbamat, må ikke anvendes i tilfælde af overfølsomhed. **Bortskaffelse:** Bortskaffes i overensstemmelse med lokale regler.
- pl **Zalecenia dotyczący przechowywania i transportu:** Chronić przed udzieleniem i nadmiernie wysokimi temperaturami. Chronić przed bezpośrednim działaniem promieni słonecznych, światła fluorescencyjnego, promieni rentgenowskich, wilgoci oraz ozonu. Przed użyciem sprawdzić czy produkt nie jest uszkodzony. Nie używać uszkodzonych rękawiczek. Zawiera ditiokarbaminiany, nie używać w przypadku nadwrażliwości. **Usuwanie:** Usuwanie zgodnie z wytycznymi miejscowych przepisów.

EU declaration of conformity available on www.medline.eu/documents/library
 Medline International France SAS, 5 rue Charles Lindbergh,
 44110 Châteaubriant, France
www.medline.com R19H7TL



Declaration of Conformity

Language of this declaration: **en English** (translations available in the following pages)

EU Declaration of conformity n° DC_Sensicare Silk
Revision n° 05
Technical file n° 09 - 24

Legal manufacturer	Medline International France SAS 5 rue Charles Lindbergh 44110 châteaubriant - France
EU representative	Not applicable
Product type	Non-sterile exam gloves : Sensicare Silk
Product Code(s)	MDS9083, MDS9084, MDS9085, MDS9086, MDS9087
GMDN Code(s)	56286

European Union Regulations:

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the following EU Regulations and/or Council Directive(s) as transposed into national laws.

Applicable regulation:	Medical Device: Regulation (EU) 2017/745 of 5 April 2017
Medical Device classification	Class I; Rule n°5
Applicable standards and/or Common Specifications are listed in technical file n°:	09
Conformity assessment procedure Certificate n° Notified Body (name/number)	Annex II and III Not applicable, self Declaration Not applicable, self Declaration

Applicable regulation:	Personal Protective Equipment: Regulation (EU) 2016/425 of 9 March 2016
Risk categories of PPE	Category III; Risk: Substances and mixtures which are hazardous to health, Harmful biological agents
Applicable standards are listed in technical file n°	24
Conformity assessment procedure(s)	
<input type="checkbox"/> Module A set out in Annex IV of Regulation	
<input checked="" type="checkbox"/> Module B set out in Annex V of Regulation EU-type examination Certificate n° Notified Body (name/number)	CE 696795 BSI (2797)
<input type="checkbox"/> Module C set out in Annex VI of Regulation	
Where applicable, the PPE is subject to the following conformity assessment procedure under surveillance of the notified body (name, number):	BSI (2797)
<input checked="" type="checkbox"/> Module C2 set out in Annex VII of Regulation : Conformity to type based on internal production control plus supervised product checks at random intervals	
<input type="checkbox"/> Module D set out in Annex VIII of Regulation : Conformity to type based on quality assurance of the production process	

Australian Regulations:

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.
Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Authorised Signatory:

Kenneth Smith
Senior QA/RA Manager

44110 Châteaubriant - France
Place

07/11/2019
Date

05.INT.02

Duration of archiving: 10 years after the end of life

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SENSICARE® SILK NITRILE

Thicker isn't always better Reliable and comfortable protection

Thicker exam gloves do not always equal more protection

SensiCare® Silk nitrile exam gloves provide the same protection as thicker gloves but at a lower thickness. SensiCare® Silk is the innovative result of new formers, an improved dipping process, and Medline's commitment to the entire exam glove production process.

With new technology in both the glove formers and dipping process, manufacturers are now able to run the production lines faster and thinner and produce a glove that still meets all the necessary physical property tests. When nitrile first was introduced, the only way they could meet these same standards was by producing a thicker glove. SensiCare® Silk gloves not only pass all necessary requirements but also provide better sensitivity to the user.

Innovations in product design allow Sensicare® Silk nitrile exam gloves to exhibit more tactile sensitivity without sacrificing protection.

FEATURES AND BENEFITS

- **The formers** – If the former a glove is made on is faulty, the glove in turn will be faulty. Medline is involved in determining the manufacturing specifications of the formers to ensure high quality gloves will be produced.
- **Nitrile examination gloves**
- **Powder-free**
- **Comfortable fit**
- **Excellent sensitivity**
- **Reliable grip**
- **Crisp blue color**
- **100% latex-free**
- **PPE certified**
- **Chemo-tested**
- **Microstop™ Film**
- **Color Coded Sizing**

Item Number	Size	Packaging
MDS9083	X-Small	200 ea/bx, 10bx/cs
MDS9084	Small	200 ea/bx, 10bx/cs
MDS9085	Medium	200 ea/bx, 10bx/cs
MDS9086	Large	200 ea/bx, 10bx/cs
MDS9087	X-Large	180 ea/bx, 10bx/cs

Recommended for use in:



Regulations and quality standards

















- Certified EN ISO13485
- Class I non-sterile Medical device according to directive 93/42/EEC
- Personal Protective Equipment Category III according to directive 89/686/EEC
- Compliance with directive 2002/72/EC for plastic materials and articles intended to come in contact with foodstuffs.










To learn more about our products, please contact your Medline representative or visit us at www.medline.com/uk



Exam Gloves Ordering Guide

Product name	Item numbers	Sizes	Colour	Texture	Thickness			Cuff length	Description	Packaging
					Fingers	Palm	Cuff			
 Restore® Nitrile* 	OAT-XS OAT-S OAT-M OAT-L OAT-XL	X-Small Small Medium Large X-Large	White	Textured fingertips	0.09 mm	0.07 mm	0.05 mm	242 mm	Nitrile, non-powdered non-sterile, with colloidal oatmeal inner coating	XS - L: 200 ea/bx, 10 bx/cs XL : 180 ea/bx, 10 bx/cs
 Restore® Sense* 	OATN32XS OATN32S OATN32M OATN32L OATN32XL	X-Small Small Medium Large X-Large	Pale mint green	Textured fingertips	0.16 mm	0.12 mm	0.10 mm	250 mm	Nitrile, non-powdered non-sterile, with colloidal oatmeal inner coating	XS - L: 250 ea/bx, 10 bx/cs XL : 230 ea/bx, 10 bx/cs
 SensiCare® Free* 	MDSFREE-XS MDSFREE-S MDSFREE-M MDSFREE-L MDSFREE-XL	X-Small Small Medium Large X-Large	Dark blue	Textured fingertips	0.09 mm	0.07 mm	0.05 mm	250 mm	Nitrile, non-powdered, non-sterile, accelerator-free	XS - L: 200 ea/bx, 10 bx/cs XL : 180 ea/bx, 10 bx/cs
 Generation Pink® Nitrile* 	PINKE2500 PINKE2501 PINKE2502 PINKE2503 PINKE2504	X-Small Small Medium Large X-Large	Pink	Textured fingertips	0.09 mm	0.07 mm	0.05 mm	240 mm	Nitrile, non-powdered, non-sterile	XS - L: 250 ea/bx, 10 bx/cs XL : 230 ea/bx, 10 bx/cs
 SensiCare® Ice* 	486800 486801 486802 486803 486804	X-Small Small Medium Large X-Large	Blue	Textured fingertips	0.09 mm	0.07 mm	0.05 mm	250 mm	Nitrile, non-powdered, non-sterile	XS - L: 200 ea/bx, 10 bx/cs XL : 180 ea/bx, 10 bx/cs
 SensiCare® Silk* 	MDS9083 MDS9084 MDS9085 MDS9086 MDS9087	X-Small Small Medium Large X-Large	Dark blue	Textured fingertips	0.09 mm	0.07 mm	0.05 mm	243 mm	Nitrile, non-powdered, non-sterile	XS - L: 200 ea/bx, 10 bx/cs XL : 180 ea/bx, 10 bx/cs
 MediGuard® Blue* 	EM5050 EM5051 EM5052 EM5053 EM5054	X-Small Small Medium Large X-Large	Light blue	Textured fingertips	0.09 mm	0.07 mm	0.05 mm	248 mm	Nitrile, non-powdered, non-sterile	XS - L: 200 ea/bx, 10 bx/cs XL : 180 ea/bx, 10 bx/cs
 SensiCare® Pro* 	PRO400XS PRO400S PRO400M PRO400L PRO400XL	X-Small Small Medium Large X-Large	Blue	Fully textured	0.23 mm	0.18 mm	0.11 mm	402 mm	Nitrile, non-powdered, non-sterile	XS - L: 50 ea/bx, 10 bx/cs XL : 50 ea/bx, 10 bx/cs

*These gloves have been tested and approved for use with chemotherapy drugs.

Product name	Item numbers	Sizes	Colour	Texture	Thickness			Cuff length	Description	Packaging
					Fingers	Palm	Cuff			
 Aloetouch® Long Cuff*	MDS195184 MDS195185 MDS195186 MDS195187	Small Medium Large X-Large	Green	Fully textured	0.16 mm	0.14 mm	0.10 mm	307 mm	Nitrile, non-powdered, non-sterile, with aloe inner coating	S - L: 50 ea/bx, 10 bx/cs XL : 50 ea/bx, 10 bx/cs
 SensiCare® Long Cuff*	MDSEXTXS MDSEXTS MDSEXTM MDSEXTL MDSEXTXL	X-Small Small Medium Large X-Large	Blue	Textured fingertips	0.14 mm	0.10 mm	0.08 mm	284 mm	Nitrile, non-powdered, non-sterile	XS - L: 100 ea/bx, 10 bx/cs XL : 90 ea/bx, 10 bx/cs
 Curad® 3G Stretch Vinyl	CUR8233 CUR8234 CUR8235 CUR8236 CUR8237	X-Small Small Medium Large X-Large	White	Smooth	0.10 mm	0.08 mm	0.06 mm	242 mm	Stretch vinyl, non-powdered non-sterile	XS - L: 100 ea/bx, 10 bx/cs XL : 90 ea/bx, 10 bx/cs
 Accutouch	MDS192073 MDS192074 MDS192075 MDS192076 MDS192077	X-Small Small Medium Large X-Large	Clear	Smooth	0.10 mm	0.08 mm	0.06 mm	254 mm	Synthetic vinyl, non-powdered, non-sterile	XS - L: 100 ea/bx, 10 bx/cs XL : 100 ea/bx, 10 bx/cs
 Eco Vinyl	MGE323 MGE324 MGE325 MGE326 MGE327	X-Small Small Medium Large X-Large	Clear	Smooth	0.09 mm	0.07 mm	0.05 mm	240 mm	Synthetic vinyl, non-powdered, non-sterile	S - L: 150 ea/bx, 10 bx/cs XL : 130 ea/bx, 10 bx/cs
 Curad® Latex	CURE8103 CURE8104 CURE8105 CURE8106 CURE8107	X-Small Small Medium Large X-Large	Beige	Textured fingertips	0.13 mm	0.11 mm	0.09 mm	246 mm	Latex, non-powdered, non-sterile	XS - L: 100 ea/bx, 10 bx/cs XL : 90 ea/bx, 10 bx/cs
 Medline Sterile Procedure Nitrile*	MDS2294 MDS2295 MDS2296 MDS2297	Small Medium Large X-Large	Blue	Textured fingertips	0.14 mm	0.11 mm	0.09 mm	296 mm	Nitrile, non-powdered, sterile	S - L: 50 pairs/bx, 6 bx/cs XL : 50 pairs/bx, 6 bx/cs

*These gloves have been tested and approved for use with chemotherapy drugs.



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