



EC Declaration of Product Conformity

Stronghold Nitrile (GM006*)

Non-sterile, powder free, nitrile single use glove

The manufacturer established in the Community declares that the new medical device and PPE described hereafter, Stronghold Nitrile, is in conformity with the provisions of Council Directive 93/42/EEC as amended, national standards EN455-1:2000, EN455-2:2015, EN455-3:2015 and EN455-4:2009 and is Class I self-certified and



is in conformity with the provisions of Council Directive 89/686/EEC as amended and where such is the case, with national standards transposing harmonized standards EN374-1:2003, EN374-2:2003, EN374-3:2003 and EN420:2003+A1:2009

is identical to the PPE which is the subject of EC certificate of conformity no. 7985 issued by SATRA Technology Centre, Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, UK (Notified Body No. 0321)

conforms to the provisions of Council Directive 89/686/EEC Article 11A under the supervision of the Notified Body, SATRA Technology Centre, (Notified Body No. 0321)

Unigloves are a market-leading manufacturer of premium quality, specialist, single use gloves.

We make and supply over 2 billion gloves annually to medical professionals, as well as specialists in the food, automotive, janitorial and care sectors.

 **Unigloves**
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 unigloves.co.uk

Product Information

Glove Care: Store between 5°C and 25°C in a cool dry environment away from direct sunlight.

Food Contact: Stronghold Nitrile gloves have been tested in accordance with EN1186. They are suitable for use with all food categories, in situations of short term repeat contact.

User Information

Cleaning: Gloves cannot be cleaned and reused. Before use, check gloves for physical damage. Do not use damaged gloves.

Fitting and sizing: Only wear products of a suitable size. Products which are either too loose or tight will restrict movement and will not provide the optimum level of protection.

Allergy advice: This product does not contain natural rubber latex but may contain low levels of residual chemical accelerators, which may cause allergic reactions.

Available sizes

Extra Small	GM0061
Small	GM0062
Medium	GM0063
Large	GM0064
Extra Large	GM0065



Chris Wahlers
Director
Unigloves (UK) Limited

Material safety data sheet

Revision 3 | 24 October 2017

Product code	GM006* The last digit of the order code is dependent on the glove size e.g. 1 = extra small, 5= extra large. N.B. Not all gloves are available in all sizes.	
1. Identification of the substance	Synthetic Nitrile	
2. Intended application	The intended application of this product are only for the purposes of examination, medical treatments and handling contaminated medical devices to prevent cross contamination between users and the patients. This product is a non-sterile single use nitrile glove and must not be used for sterile applications.	
3. Composition / ingredients	Nitrile Latex, Sulphur, ZnO, TiO ₂ , ZDEC, Colour Pigment	
4. Identification of hazards	This product contains accelerators and may cause allergic reactions. The colour pigment used is not classified as hazardous.	
5. First-aid measures	In case of rashes or any other discomfort appear, discontinue use immediately and wash hand with plenty of water. Consult physician.	
6. Fire-fighting measures	Extinguishing media: water, foam or dry powder. In case of fire wear respiratory protection equipment.	
7. Accidental release measures	No special procedure required. Sweep into appropriate container for disposal. Accidentally released gloves shall not be reused.	
8. Handling and storage	Store in cool and dry area. Protect from sources of heat, direct sun light and UV light.	
9. Exposure control and personal protection	Discontinue use if rashes or other sign of discomfort occur. Thin cotton gloves may be used as liner to prevent direct skin contact.	
10. Physical and chemical properties	Form:	Elastomer
	Colour:	Purple
	Odour:	Inherent
	Surface:	Fingertip textured
	Solubility in water:	Insoluble
	Soluble in:	None identified
11. Stability and reactivity	pH value:	Neutral
	Stability:	Stable
	Materials to avoid:	Acrylates, ketones, halogenated hydrocarbons, strong oxidizing and reducing agents
	Conditions to avoid:	Sunlight, UV light and heat
	Hazardous decomposition chemicals:	Acetone, acrylonitrile, aliphatic and aromatic hydrocarbons, alcohols, ammonia, butadiene, carbon disulphide, carbon and nitrogen oxides, formaldehyde, hydrogen cyanide, naphthalene, phenol, and other compounds
12. Toxicology information	Skin irritation:	None identified
	Dermal contact sensitisation:	This product contains accelerators and may cause allergic reactions in some individuals
13. Ecological information	Non-biodegradable	
14. Disposal considerations	Landfill; dispose of in accordance with local and national regulations. May be incinerated in a suitable facility using heat recovery	
15. Transport information	Not classified	

Material safety data sheet

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16. Regulatory information

Primary regulation:	MDD 93/42/EEC and PPED 89/686/EEC
Classification:	Class I non-sterile medical device / Complex design (Cat III) PPE
Risk phrases:	N/A
Safety phrases:	If it is suspected you may have an allergy, discontinue use of the gloves and seek medical advice.

17. Other information

None

The data shown here is based on current knowledge and experience. The purpose of this safety data sheet is to describe the product in terms of its safety requirements. The data does not signify or imply any warranty with regard to the product properties or performance.

Product specification sheet

Revision 5 | 24 October 2017

1.	Product code	GM006*																																		
2.	Product description	Stronghold Purple Nitrile																																		
3.	Material	Nitrile																																		
4.	Inspection parameters	<table border="1"> <thead> <tr> <th>Criteria</th> <th>Inspection level</th> <th>AQL</th> <th colspan="3">Standard</th> </tr> </thead> <tbody> <tr> <td>Dimensions</td> <td>S-2</td> <td>4</td> <td colspan="3">EN455-2</td> </tr> <tr> <td>Physical properties</td> <td>S-2</td> <td>4</td> <td colspan="3">EN455-2</td> </tr> <tr> <td>Water tight test (1,000ml)</td> <td>G-1</td> <td>0.65</td> <td colspan="3">EN455-1</td> </tr> <tr> <td>Visual defects</td> <td>G-1</td> <td>2.5</td> <td colspan="3">In-house</td> </tr> </tbody> </table>					Criteria	Inspection level	AQL	Standard			Dimensions	S-2	4	EN455-2			Physical properties	S-2	4	EN455-2			Water tight test (1,000ml)	G-1	0.65	EN455-1			Visual defects	G-1	2.5	In-house		
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8.	Proteins	None																																		
9.	Powder residue	Maximum 2.0 mg / glove																																		
10.	Cuff type	Beaded																																		
11.	Design	Ambidextrous																																		
12.	Surface	Fingertip textured																																		
13.	Colour	Purple																																		
14.	Quality assurance	Manufactured under ISO 9001:2008 and 13485:2012																																		

The above data represents the product norm, which may be changed without notice and is intended as a guide only.

Warehouse data sheet

Revision 3 | 25 October 2017

Product code

GM006*

Individual Boxes

Product Code	Size	Barcode (EAN-13)	Weight (g.)	Quantity (gloves)	Dimensions (mm)
GM0061	Extra Small	5060264115860	615.00	100	240 (L) x 120 (W) x 70 (H)
GM0062	Small	5060264115877	665.00	100	240 (L) x 120 (W) x 70 (H)
GM0063	Medium	5060264115884	715.00	100	240 (L) x 120 (W) x 70 (H)
GM0064	Large	5060264115891	765.00	100	240 (L) x 120 (W) x 70 (H)
GM0065	Extra Large	5060264115907	815.00	100	240 (L) x 120 (W) x 70 (H)

Cartons

Product Code	Size	Barcode (EAN-13)	Weight (kg)	Quantity (gloves)	Dimensions (mm)
GM0061	Extra Small	5060264115914	6.55	10 x 100	365 (L) x 250 (W) x 250 (H)
GM0062	Small	5060264115921	7.05	10 x 100	365 (L) x 250 (W) x 250 (H)
GM0063	Medium	5060264115938	7.55	10 x 100	365 (L) x 250 (W) x 250 (H)
GM0064	Large	5060264115945	8.05	10 x 100	365 (L) x 250 (W) x 250 (H)
GM0065	Extra Large	5060264115952	8.55	10 x 100	365 (L) x 250 (W) x 250 (H)

Pallets

Product Code	Size	Volume (m ³)	Weight (kg)	Quantity (cartons)	Dimensions (mm)
GM0061	Extra Small	1.92	570.20	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GM0062	Small	1.92	612.20	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GM0063	Medium	1.92	654.20	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GM0064	Large	1.92	696.20	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GM0065	Extra Large	1.92	738.20	84	1,000 (L) x 1,200 (W) x 1,900 (H)

Containers

Product Code	Size	Container Quantity (cartons)		
		20ft	40ft	40ft High Cube
GM0061	Extra Small	1350	2763	3050
GM0062	Small	1350	2763	3050
GM0063	Medium	1350	2763	3050
GM0064	Large	1350	2763	3050
GM0065	Extra Large	1350	2763	3050