

EC Declaration of Product Conformity

12 colour Pearl Nitrile range (GP0***)

Non-sterile, powder free, nitrile single use glove

The manufacturer established in the Community declares that the new medical device and PPE described hereafter, Pearl 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 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, EN16523-1:2015 and EN420:2003+A1:2009

is identical to the PPE which is the subject of EC certificate of conformity no. 21256295001 issued by TUV Rheinland LGA Products GmbH, Tillystraße 2, 90431, Nürnberg, Germany (Notified Body No. 0197)

conforms to the provisions of Council Directive 89/686/EEC Article 11A under the supervision of the Notified Body, TUV Rheinland LGA Products GmbH, (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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Product Information

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

Food Contact: Pearl 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	GP0**1
Small	GP0**2
Medium	GP0**3
Large	GP0**4
Extra Large	GP0**5

** denotes colour as follows;

01 Blue / 02 White / 03 Black / 04 Green /
05 Pink / 06 Red / 07 Violet / 08 Sapphire /
09 Opal / 10 Peach / 11 Yellow /
12 Burgundy



Chris Wahlers

Director

Unigloves (UK) Limited

CE 0321 

Material safety data sheet

Revision 3 | 24 October 2017

Product code	GP011* 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:	Yellow
	Odour:	Inherent
	Surface:	Fingertip textured
	Solubility in water:	Insoluble
	Soluble in:	None identified
	pH value:	Neutral
11. Stability and reactivity	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

Revision 3 | 24 October 2017

16. Regulatory information

Primary regulation:	MDD 93/42/EEC and PPED 89/686/EEC
Classification:	Class I non-sterile medical device / Minimal risk 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	GP011*																																		
2.	Product description	Yellow Pearl 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>1.5</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	1.5	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	Yellow																																		
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

GP011*

Individual Boxes

Product Code	Size	Barcode (EAN-13)	Weight (g.)	Quantity (gloves)	Dimensions (mm)
GP0111	Extra Small	5060264118946	315.00	100	240 (L) x 120 (W) x 60 (H)
GP0112	Small	5060264118953	365.00	100	240 (L) x 120 (W) x 60 (H)
GP0113	Medium	5060264118960	415.00	100	240 (L) x 120 (W) x 60 (H)
GP0114	Large	5060264118977	465.00	100	240 (L) x 120 (W) x 60 (H)
GP0115	Extra Large	5060264118984	515.00	100	240 (L) x 120 (W) x 60 (H)

Cartons

Product Code	Size	Barcode (EAN-13)	Weight (kg)	Quantity (gloves)	Dimensions (mm)
GP0111	Extra Small	5060264118991	3.50	10 x 100	315 (L) x 250 (W) x 250 (H)
GP0112	Small	5060264119004	4.00	10 x 100	315 (L) x 250 (W) x 250 (H)
GP0113	Medium	5060264119011	4.50	10 x 100	315 (L) x 250 (W) x 250 (H)
GP0114	Large	5060264119028	5.00	10 x 100	315 (L) x 250 (W) x 250 (H)
GP0115	Extra Large	5060264119035	5.50	10 x 100	315 (L) x 250 (W) x 250 (H)

Pallets

Product Code	Size	Volume (m ³)	Weight (kg)	Quantity (cartons)	Dimensions (mm)
GP0111	Extra Small	2.07	387.50	105	1,000 (L) x 1,200 (W) x 1,900 (H)
GP0112	Small	2.07	440.00	105	1,000 (L) x 1,200 (W) x 1,900 (H)
GP0113	Medium	2.07	492.50	105	1,000 (L) x 1,200 (W) x 1,900 (H)
GP0114	Large	2.07	545.00	105	1,000 (L) x 1,200 (W) x 1,900 (H)
GP0115	Extra Large	2.07	597.50	105	1,000 (L) x 1,200 (W) x 1,900 (H)

Containers

Product Code	Size	Container Quantity (cartons)		
		20ft	40ft	40ft High Cube
GP0111	Extra Small	1557	3186	3540
GP0112	Small	1557	3186	3540
GP0113	Medium	1557	3186	3540
GP0114	Large	1557	3186	3540
GP0115	Extra Large	1557	3186	3540