

EC Declaration of Product Conformity

Paragon+ Nitrile (GL001*)

Non-sterile, powder free, nitrile single use glove

The manufacturer established in the Community declares that the new medical device and PPE described hereafter, Paragon+ 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. 7986 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**
Lakeside Park
Neptune Close
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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: Paragon+ 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	GL0011
Small	GL0012
Medium	GL0013
Large	GL0014
Extra Large	GL0015



Chris Wahlers

Director

Unigloves (UK) Limited

CE 0321 

Material safety data sheet

Revision 3 | 24 October 2017

Product code	GL001* 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:	Blue
	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	GL001*																																		
2.	Product description	Paragon + Blue Nitrile (EC)																																		
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	Blue																																		
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

GL001*

Individual Boxes

Product Code	Size	Barcode (EAN-13)	Weight (g.)	Quantity (gloves)	Dimensions (mm)
GL0011	Extra Small	5060264115761	725.00	50	260 (L) x 120 (W) x 60 (H)
GL0012	Small	5060264115778	775.00	50	260 (L) x 120 (W) x 60 (H)
GL0013	Medium	5060264115785	825.00	50	260 (L) x 120 (W) x 60 (H)
GL0014	Large	5060264115792	875.00	50	260 (L) x 120 (W) x 60 (H)
GL0015	Extra Large	5060264115808	925.00	50	260 (L) x 120 (W) x 60 (H)

Cartons

Product Code	Size	Barcode (EAN-13)	Weight (kg)	Quantity (gloves)	Dimensions (mm)
GL0011	Extra Small	5060264115815	7.65	10 x 50	320 (L) x 255 (W) x 275 (H)
GL0012	Small	5060264115822	8.15	10 x 50	320 (L) x 255 (W) x 275 (H)
GL0013	Medium	5060264115839	8.65	10 x 50	320 (L) x 255 (W) x 275 (H)
GL0014	Large	5060264115846	9.15	10 x 50	320 (L) x 255 (W) x 275 (H)
GL0015	Extra Large	5060264115853	9.65	10 x 50	320 (L) x 255 (W) x 275 (H)

Pallets

Product Code	Size	Volume (m ³)	Weight (kg)	Quantity (cartons)	Dimensions (mm)
GL0011	Extra Small		708.50	90	1,000 (L) x 1,200 (W) x 1,900 (H)
GL0012	Small		753.50	90	1,000 (L) x 1,200 (W) x 1,900 (H)
GL0013	Medium		798.50	90	1,000 (L) x 1,200 (W) x 1,900 (H)
GL0014	Large		843.50	90	1,000 (L) x 1,200 (W) x 1,900 (H)
GL0015	Extra Large		888.50	90	1,000 (L) x 1,200 (W) x 1,900 (H)

Containers

Product Code	Size	Container Quantity (cartons)		
		20ft	40ft	40ft High Cube
GL0011	Extra Small			2300
GL0012	Small			2300
GL0013	Medium			2300
GL0014	Large			2300
GL0015	Extra Large			2300