

EC Declaration of Product Conformity

Supergrip Latex (GM002*)

Non-sterile, powder free, latex single use glove

The manufacturer established in the Community declares that the new medical device and PPE described hereafter, Supergrip Latex, 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. 7061 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.

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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: Supergrip Latex 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 contains natural rubber latex and may contain low levels of residual chemical accelerators, which may cause allergic reactions.

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Available sizes

Extra Small	GM0021
Small	GM0022
Medium	GM0023
Large	GM0024
Extra Large	GM0025

Chris Wahlers

Director

Unigloves (UK) Limited

Unigloves Material safety data sheet Revision 3 | 24 October 2017

	Product code	GM002* 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	Natural rubber latex					
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 natural rubber latex glove and must not be used for sterile applications.					
3.	Composition / ingredients	Calcium Carbonate, Natural Rubber Latex, ZDBC, ZDEC, Zinc Oxide, Wingstay-L, Sulphur, Titanium Dioxide.					
4.	Identification of hazards	This product contains natu	ral rubber latex a	nd a	ccelerators and may cause allergic reactions.		
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	Form:	Elastomer				
	properties	Colour:	Natural				
		Odour:	Inherent				
		Surface:	Microroughene	d			
		Solubility in water:	Insoluble				
		Soluble in:	None identified				
		pH value:	Neutral				
11.	Stability and reactivity	Stability:		Sta	ble		
	, , , , , , , , , , , , , , , , , , ,	Materials to avoid:		Pet	roleum based solvents		
		Conditions to avoid:		Sur	nlight, UV light and heat		
		Hazardous decomposition chemicals:			rbon and sulphur oxides, aliphatic and aromatic drocarbons		
12.	Toxicology information	Skin irritation:			None identified		
	ŭ.	Dermal contact sensitisation:			This product contains natural rubber latex and accelerators and may cause allergic reactions in some individuals		
13.	Ecological information	Biodegradable					
14.	Disposal considerations	Landfill; dispose of in acco suitable facility using heat		and i	national regulations. May be incinerated in a		
15.	Transport information	Not classified					

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None

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16.	Regul	atorv	inforn	nation
10.	Regui	atory	11110111	iatioi

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

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.

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1.	Product code	GM002*							
2.	Product description	Supergrip Latex	Supergrip Latex						
3.	Material	Latex							
4.	Inspection parameters	Criteria Inspection level AQL Standard							
		Dimensions S-2 4 EN455-2						EN455-2	
		Physical properties S-2 4 EN455-2						EN455-2	
		Water tight test (1,000ml) G-1 1.5 EN455-1						EN455-1	
		Visual defects G-1 2.5 In-house						In-house	
5.	Glove dimensions	Dimensions			Size (mm)				
		Difficusions	Dimensions XS S M					XL	
		Product code GM0021 GM0022 GM0023 G					4	GM0025	
		Palm width 75 ± 5 80 ± 10 95				110 ± 1	0	≥ 110	
		Length	≥ 240	≥ 240	≥ 240	≥ 240		≥ 240	
6.	Glove thickness	Point of thickness measurement Nominal single wall (mm)						le wall (mm)	
		Cuff (at beaded end)				0.0	18	
		Palm (at centre of p	alm)				0.1	1	
		Fingertip (at fingerti	p)				0.1	3	
7.	Physical properties	Paramete	rs	Before a	aging	A	fter a	aging	
		Median force at bre	ak (N)	Min 6	5.0		Min	6.0	
		Tensile strength (Mi	Pa)	Min 1	8.0		Min ′	14.0	
		Ultimate elongation	(%)	Min 6	50		Min	500	
8.	Proteins	< 50 μg/g extractab	le latex prote	ins					
9.	Powder residue	Maximum 2.0 mg / glove							
10.	Cuff type	Beaded							
11.	Design	Ambidextrous							
12.	Surface	Microroughened							
13.	Colour	Natural							
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.



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Troduct code Giwooz	Product code	GM002*
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Individual Boxes

Product Code	Size	Barcode (EAN-13)	Weight (g.)	Quantity (gloves)	Dimensions (mm)
GM0021	Extra Small 5060264110308		575.00	100	240 (L) x 120 (W) x 70 (H)
GM0022	Small	5060264110315	625.00	100	240 (L) x 120 (W) x 70 (H)
GM0023	Medium 5060264110322		675.00	100	240 (L) x 120 (W) x 70 (H)
GM0024	Large	5060264110339	725.00	100	240 (L) x 120 (W) x 70 (H)
GM0025	Extra Large	5060264110346	775.00	100	240 (L) x 120 (W) x 70 (H)

Cartons

Product Code	Size	Barcode (EAN-13)	Weight (kg)	Quantity (gloves)	Dimensions (mm)
GM0021	Extra Small	5060264110353	6.15	10 x 100	365 (L) x 250 (W) x 250 (H)
GM0022	Small	5060264110360	6.65	10 x 100	365 (L) x 250 (W) x 250 (H)
GM0023	Medium	5060264110377	7.15	10 x 100	365 (L) x 250 (W) x 250 (H)
GM0024	Large	5060264110384	7.65	10 x 100	365 (L) x 250 (W) x 250 (H)
GM0025	Extra Large	5060264110391	8.15	10 x 100	365 (L) x 250 (W) x 250 (H)

Pallets

Product Code	Size	Volume (m³)	Weight (kg)	Quantity (cartons)	Dimensions (mm)
GM0021	Extra Small	1.92	536.60	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GM0022	Small	1.92	578.60	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GM0023	Medium	1.92	620.60	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GM0024	Large	1.92	662.60	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GM0025	Extra Large	1.92	704.60	84	1,000 (L) x 1,200 (W) x 1,900 (H)

Containers

Container Quantity (cartons)

Product Code	Size	20ft	40ft	40ft High Cube
GM0021	Extra Small	1350	2763	3050
GM0022	Small	1350	2763	3050
GM0023	Medium	1350	2763	3050
GM0024	Large	1350	2763	3050
GM0025	Extra Large	1350	2763	3050