### Unigloves EC Declaration of Product Conformity Vitality Latex Scented (GD001\*)

Non-sterile, powder free, latex single use glove

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

### 다 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: Vitality Latex Scented 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.



Available sizes	
Extra Small	GD0011
Small	GD0012
Medium	GD0013
Large	GD0014
Extra Large	GD0015

Chris Wahlers **Director** Unigloves (UK) Limited

# Unigloves Material safety data sheet

Revision 3 | 24 October 2017

	Product code	GD001* 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	treatments and handling c users and the patients. Th	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	Natural Rubber Latex, ZDB Pigment, Vitamin E Acetate			Sulphur, TiO2, Anti-Oxidant, Wax, Colour ermint Flavour.		
4.	Identification of hazards	This product contains natu	ıral rubber latex a	and a	ccelerators and may cause allergic reactions.		
5.	First-aid measures	In case of rashes or any ot with plenty of water. Const		opear	, discontinue use immediately and wash hand		
6.	Fire-fighting measures	Extinguishing media: wate equipment.	r, foam or dry pov	wder	In case of fire wear respiratory protection		
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:	Green				
		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:			croleum based solvents		
		Conditions to avoid:			nlight, UV light and heat		
		Hazardous decomposition chemicals:     Carbon and sulphur oxides, aliphatic and aromathydrocarbons					
12.	Toxicology information	Skin irritation:			None identified		
		Dermal contact sensitisation:			This product contains natural rubber latex and 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					

### Unigloves 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.

# Unigloves Product specification sheet Revision 5 | 24 October 2017

1.	Product code	GD001*							
2.	Product description	Vitality scented Green Latex (Lano-E)							
3.	Material	Latex							
4.	Inspection parameters	Criteria		Inspection leve	el AC	ρL		Standard	
		Dimensions		S-2	4	4		EN455-2	
		Physical properties		S-2	S-2 4		4 EN455-2		
		Water tight test (1,0	00ml)	G-1	1.	I.5 EN455-		EN455-1	
		Visual defects		G-1	2.	5		In-house	
5.	Glove dimensions	Dimonsions			Size (mm)				
		Dimensions	XS	S	М	L		XL	
		Product code	GD0011	GD0012	GD0013	GD001	4	GD0015	
		Palm width	75 ± 5	80 ± 10	95 ± 10	110 ± 1	0	≥ 110	
		Length	≥ 240	≥ 240	≥ 240	≥ 240		≥ 240	
6.	Glove thickness	Point	of thickness	measurement		Nomina	sing	le wall (mm)	
		Cuff (at beaded end) 0.09							
		Palm (at centre of palm)   0.12							
		Fingertip (at fingerti	ip)				0.1	3	
7.	Physical properties	Parameter	rs	Before	aging	A	fter	aging	
		Median force at break (N)		Min 6.0		Min 6.0		6.0	
		Tensile strength (M	Pa)	Min 1	8.0	Min 14.0			
		Ultimate elongation	1 (%)	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	Green							
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.

## Unigloves Warehouse data sheet

Revision 3 | 25 October 2017

Product code

GD001\*

### Individual Boxes

Product Code	roduct Code Size Barcode (EAN-13) Weight (g		Weight (g.)	Quantity (gloves)	Dimensions (mm)
GD0011	Extra Small	5060264112012	575.00	100	240 (L) x 120 (W) x 70 (H)
GD0012	Small	5060264112029	625.00	100	240 (L) x 120 (W) x 70 (H)
GD0013	Medium	5060264112036	675.00	100	240 (L) x 120 (W) x 70 (H)
GD0014	Large	5060264112043	725.00	100	240 (L) x 120 (W) x 70 (H)
GD0015	Extra Large	5060264112050	775.00	100	240 (L) x 120 (W) x 70 (H)

### Cartons

Product Code	Size	Barcode (EAN-13)	Weight (kg)	Quantity (gloves)	Dimensions (mm)
GD0011	Extra Small	5060264112067	6.15	10 x 100	365 (L) x 250 (W) x 250 (H)
GD0012	Small	5060264112074	6.65	10 x 100	365 (L) x 250 (W) x 250 (H)
GD0013	Medium	5060264112081	7.15	10 x 100	365 (L) x 250 (W) x 250 (H)
GD0014	Large	5060264112098	7.65	10 x 100	365 (L) x 250 (W) x 250 (H)
GD0015	Extra Large	5060264112104	8.15	10 x 100	365 (L) x 250 (W) x 250 (H)

### Pallets

Product Code	Size	Volume (m <sup>3</sup> )	Weight (kg)	Quantity (cartons)	Dimensions (mm)
GD0011	Extra Small	1.92	536.60	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GD0012	Small	1.92	578.60	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GD0013	Medium	1.92	620.60	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GD0014	Large	1.92	662.60	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GD0015	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
GD0011	Extra Small 1350		2763	3050
GD0012	Small	1350	2763	3050
GD0013	Medium	1350	2763	3050
GD0014	Large	1350	2763	3050
GD0015	Extra Large	1350	2763	3050