Certificate of Registration

nqa global assurance

This is to certify that the Quality Management System of

Unigloves Sdn Bhd
Lot 18374,Jalan Perusahaan 3 Kamunting
Industrial Estate,34600 Perak Darul Ridzuan
Malaysia

applicable to

Latex exam glove and Nitrile exam glove

have been accessed and registered by NQA against the provisions of

ISO 9001:2008

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.
Please consult the website: www.snqa.com.cn

Certificate Number **35167**

Date: 27 June 2014
Valid Until: 27 June 2020
EAC Code: 14

Head of NQA

UKAS QUALITY MANAGEMENT
015

Certificate MY96/7530

The management system of

Unigloves Sdn Bhd (Berhard)

Lot 18374 , Jalan Perusahaan 3 Kamunting Industrial Estate
34600 Perak Darul Ridzuan,
MALAYSIA

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Design & Manufacture of Household, Industrial / Working Gloves.
Manufacture of Non-Sterile Examination Gloves.
Manufacture of Powder-Free Vinyl Gloves.

This certificate is valid from 25 April 2018 until 24 April 2021 and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 14. Certified since 26 June 1996

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 9001 2015 0818

Unigloves

EC Declaration of Product Conformity

Comfort Latex (GM003*)

Non-sterile, powder free, latex single use glove

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

Unigloves
Lakeside Park
Neptune Close
Rochester
Kent
ME2 4LT

01634 726 516

unigloves.co.uk

Product Information

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

Food Contact: Comfort 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.

CE 0321

Available sizes	
Extra Small	GM0031
Small	GM0032
Medium	GM0033
Large	GM0034
Extra Large	GM0035

Chris Wahlers
Director
Unigloves

Unigloves

Material safety data sheet

Revision 3 | 24 October 2018

	Product code	GM003* 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 natural rubber latex and accelerators 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 properties

Form:	Elastomer
Colour:	Natural
Odour:	Inherent
Surface:	Smooth
Solubility in water:	Insoluble
Soluble in:	None identified
pH value:	Neutral

11. Stability and reactivity

Stability:	Stable
Materials to avoid:	Petroleum based solvents
Conditions to avoid:	Sunlight, UV light and heat
Hazardous decomposition chemicals:	Carbon and sulphur oxides, aliphatic and aromatic hydrocarbons

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	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

Revision 3 | 24 October 2018

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 2018

1. Product code: GM003*

2. Product description: Comfort Latex (Double chlorinated)

3. Material: Latex

4. Inspection parameters

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

5. Glove dimensions

Dimensions	Size (mm)				
	XS	S	M	L	XL
Product code	GM0031	GM0032	GM0033	GM0034	GM0035
Palm width	75 ± 5	80 ± 10	95 ± 10	110 ± 10	≥ 110
Length	≥ 240	≥ 240	≥ 240	≥ 240	≥ 240

6. Glove thickness

Point of thickness measurement	Nominal single wall (mm)
Cuff (at beaded end)	0.09
Palm (at centre of palm)	0.12
Fingertip (at fingertip)	0.13

7. Physical properties

Parameters	Before aging	After aging
Median force at break (N)	Min 6.0	Min 6.0
Tensile strength (MPa)	Min 18.0	Min 14.0
Ultimate elongation (%)	Min 650	Min 500

8. Proteins: < 50 µg/g extractable latex proteins

9. Powder residue: Maximum 2.0 mg / glove

10. Cuff type: Beaded

11. Design: Ambidextrous

12. Surface: Smooth

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.

Unigloves

Warehouse data sheet

Revision 3 | 25 October 2018

Product code	GM003*

Individual Boxes

Product Code	Size	Barcode (EAN-13)	Weight (g.)	Quantity (gloves)	Dimensions (mm)
GM0031	Extra Small	5060264116461	575.00	100	240 (L) x 120 (W) x 70 (H)
GM0032	Small	5060264116478	625.00	100	240 (L) x 120 (W) x 70 (H)
GM0033	Medium	5060264116485	675.00	100	240 (L) x 120 (W) x 70 (H)
GM0034	Large	5060264116492	725.00	100	240 (L) x 120 (W) x 70 (H)
GM0035	Extra Large	5060264116508	775.00	100	240 (L) x 120 (W) x 70 (H)

Cartons

Product Code	Size	Barcode (EAN-13)	Weight (kg)	Quantity (gloves)	Dimensions (mm)
GM0031	Extra Small	5060264116515	6.15	10 x 100	365 (L) x 250 (W) x 250 (H)
GM0032	Small	5060264116522	6.65	10 x 100	365 (L) x 250 (W) x 250 (H)
GM0033	Medium	5060264116539	7.15	10 x 100	365 (L) x 250 (W) x 250 (H)
GM0034	Large	5060264116546	7.65	10 x 100	365 (L) x 250 (W) x 250 (H)
GM0035	Extra Large	5060264116553	8.15	10 x 100	365 (L) x 250 (W) x 250 (H)

Pallets

Product Code	Size	Volume (m^3)	Weight (kg)	Quantity (cartons)	Dimensions (mm)
GM0031	Extra Small	1.92	536.60	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GM0032	Small	1.92	578.60	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GM0033	Medium	1.92	620.60	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GM0034	Large	1.92	662.60	84	1,000 (L) x 1,200 (W) x 1,900 (H)
GM0035	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
GM0031	Extra Small	1350	2763	3050
GM0032	Small	1350	2763	3050
GM0033	Medium	1350	2763	3050
GM0034	Large	1350	2763	3050
GM0035	Extra Large	1350	2763	3050

Unigloves

EC Declaration of Product Conformity

Unicare Soft Blue Vinyl (GS008*)

Unicare Soft Clear Vinyl (GS006*)

Unicare Soft Green Vinyl (GS012*)

Unicare Soft Red Vinyl (GS011*)

Unicare Soft Yellow Vinyl (GS010*)

Unicare Soft Stretch Vinyl (GS013*)

Non-sterile, powder free, vinyl single use glove

The manufacturer established in the Community declares that the new PPE described hereafter, Unicare Soft Vinyl, is in conformity with the provisions of Council Directive 89/686/EEC as amended and where such is the case, with national standard transposing harmonized standard EN420:2003+A1:2009 and has been self-certified as simple design

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
Rochester
Kent
ME2 4LT

01634 726 516

unigloves.co.uk

Product Information

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

Food Contact: Unicare Soft Vinyl gloves have been tested in accordance with EN1186. They are suitable for use with all food categories (except fatty foods), 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.

Available sizes

Small	GS0**2
Medium	GS0**3
Large	GS0**4
Extra Large	GS0**5

* denotes colour as follows;

08 Blue / 06 Clear / 12 Green / 11 Red / 10 Yellow / 13 Stretch

Chris Wahlers
Director
Unigloves (UK) Limited

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 18, 2017

UG Global Resources Sdn. Bhd.
% Kenneth Stanton
President
UG Healthcare (USA) Inc.
1565 Sunflower Ave
Costa Mesa, California 92626

Re: K162510
Trade/Device Name: Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: June 20, 2017
Received: January 19, 2017

Dear Kenneth Stanton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark S. Fellman -S

for

Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162510

Device Name
Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue

Indications for Use *(Describe)*
Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue is a disposable device intended for medical purposes that is worn on the examiner 's hand or finger to prevent contamination between the patient and the examiner

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SUMMARY

PREMARKET 510(k) NOTIFICATION
Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue
K162510

Submission Applicant:

UG Global Resources Sdn Bhd
1st Floor No. 18
Jalan Dato' Abd Rahman 70000 Seremban
Negeri Sembilan Darul Khusus, Malaysia
Telephone No.: 60-06-6772751
Fax: 60-06-6772755

Official Correspondent:
Kenneth J. Stanton, President
UG Healthcare (USA) Inc. 1565 Sunflower Avenue Costa Mesa, Ca 92626
Tel: (714)444-2248
Fax: (714)444-2271

Date: June 8, 2017

Description of the Device: Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue

Trade Name:
Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue

Common Name: Nitrile Examination Gloves
Classification Name: Patient Examination Glove (per 21 CFR 880.6250)
Class 1: Powder-Free Nitrile examination glove LZA that meets all of the requirements of ASTM 6319-10.

Predicative Devices (K112012):Non-Sterile, Powder-Free, Blue, Nitrile Examination Gloves

Device Description: The subject device of this submission is a Nitrile Examination Glove. The glove is non-sterile and meets the recommendations of ASTM 6319-10 . The device is Blue in color.

Indications for Use: Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between the patient and the examiner.

SUMMARY

PREMARKET 510(k) NOTIFICATION
Non-Sterile, Powder-Free, Nitrile Examination Gloves, Blue

Summary of Technological Characteristics:
Material: Nitrile Cuff: Beaded Powder Residue: Maximum 2mg/glove

Characteristics	Standards	Device Performance
Dimensions	ASTM D 6319-10	Inspection Level-S-2 AQL4.0
Physical Properties	ASTM D 6319-10	Inspection Level-S-2 AQL4.0
Freedom from Pinholes – Water Tight Test 1000ML	ASTM D 6319-10 ASTM D 5151-06	Inspection Level-G-1 AQL 1.5
Powder-Free Residue-	ASTM D 6319-10 ASTM D 6124-06	Maximum 2mg/glove
Biocompatibility	Dermal Sensitization (as per ISO 10993-10 Primary Skin Irritation Test (as per 16 CFR Part 1500)	Not a contact skin sensitizer Not a primary skin irritant

Packaging: 100 pieces per dispenser box, 10 boxes per case, 1,000 gloves per case

Sizes: XS -XL

Substantial Equivalence Table-

		Color	Material	Biocompatibility Tests	ASTM D3578-05(2015) Tensile Strength (MPa)	ASTM D3578-05(2015) Elongation %
Subject Device K162510		Blue	Nitrile	ISO 10993-10 - Primary Irritation Test- Under the conditions of the study, the device is non-irritating	Before Aging- min 14.0	Before Aging - min. 500
				ISO 10993-10 - Dermal Sensitization Assay - Under the conditions of the study, the device is a non-sensitizer	After Aging - min 14.0	After Aging - min. 400
Predicate Device K112012		Blue	Nitrile	ISO 10993-10 - Dermal Sensitization Assay - Under the conditions of the study, the device is a non-sensitizer	Before Aging- min 14.0	Before Aging- min. 500
				ISO 10993-10 - Primary Irritation Test- Under the conditions of the study, the device is non-irritating	After Aging- min 14.0	After Aging - min. 400

		Dimensions	Waterleak	Powder Content	
Subject Device K162510		Palm Width - 95mm +/-10 Medium size Length: 240mm min Thickness; Min .05mm Palm and finger	AQL 1.5	Max 2.0mg/glove Avg 1.0mg/glove	
Predicate Device K112012		Palm Width- 95mm +/- 10 Medium size Length : 240mm min Thickness: Min .15mm Palm and Min .17mm finger	AQL 1.5	Max 2.0mg/glove Avg .22mg/glove	

		Sizes	Single Use	Indications for Use
Subject Device K162510		XS-XL	Yes	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner
Predicate Device K112012		XS-XL	Yes	A patient examination glove is a disposable device intended for Medical Purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner

Comparisons-Both K162510 and K112012 are Non-Sterile, Powder-Free Nitrile Examination Gloves. Both have the same specifications except for thickness, both have the same AQL 1.5 for pinholes and similar powder content. Both gloves have passed the Biocompatibility Test. Additionally, both devices have similar tensile strength and elongation performance.

Conclusion:

This product is as safe, as effective, and performs as well or better than the legally marketed device K112012 (Non-Sterile, Powder-Free Blue, Nitrile Examination Gloves).