Manufacturer	[redacted]
Origin	Malaysia
510 (K)/MDL	K133168/D222519
Expiry Date	5 years
Description	Nitrile Examination Gloves
Type	Powder free and non sterile
Design and Feature	Ambidextrous, textured surface (E5) and beaded cuff
Colour	Cobalt Blue
Length	235mm (±0.5mm)
Weight	3.5grams (± 0.3 grams) (Size M)
Size	Medium, Large

Product performance	
(i)	Medical device : in compliance with European Medical Devices Directive 94/42/EEC (CE Class 1)
(ii)	EN 455 Parts 1,2 3,4
(iii)	PPE of complex design category III, in European regulation (EU) 2016/425, type tested to EN420:2003+A1:2009, EN ISO 374-1:2016 TYPE B, EN 374-2:2014, EN 374-3:2013, EN374-5:2016 & EN 16523-1:2015, CE 2797
(iv)	ASTM D6319

Quality Assurance	
(i)	US FDA Quality System Regulation
(ii)	ISO 9001:2015 Quality Management System
(iii)	EN ISO 13485:2016 & EN ISO 13485:2016 Quality Management System
(iv)	TGA ARTG Entry 214934

bsi.

By Royal Charter

EU Type Examination Certificate

This is to certify that:

[redacted]
43900
Malaysia

Holds Certificate Number: CE 688314

In respect of:

Powder Free Nitrile Gloves

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

Previous Notified Body: BSI 0086

First Issued: 2018-04-26

Latest Issue: 2019-09-12

Effective Date: 2019-09-12

Expiry Date: 2023-04-26

PRODUCTS
RvA C 646

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EU Type Examination Certificate

No. CE 688314

Product Specification

Model – Nitrile gloves

Classification: Protective glove for use against chemical and micro-organism hazards.

Description: Powder Free Nitrile Disposable Protective Gloves manufactured from 100% nitrile synthetic rubber latex (Acylonitrile-butadiene) not containing natural rubber latex. Inner surface of gloves is smooth surface that assists in donning the gloves without using lubricant such as powder on the glove surface. The glove is available as either Sterile or Non-Sterile as indicated.

The main features of this protective glove are:
- Beaded cuff
- Micro-organisms penetration resistance
- Chemical permeation resistance
- Diamond embossed of palm/back of hand (Ambidextrous)

Models in range: Nitrile gloves.

Category: Category III – complex

Applicable Standards:
General requirements for gloves to EN 420:2003 +A1:2009
Protective gloves again chemicals & micro-organisms to EN ISO 374-1:2016
Resistance to penetration to EN 374-2:2014
Determination of resistance to permeation by chemicals tested to EN 16523-1:2015
Resistance to penetration by blood borne tested to EN ISO 374-5:2016
Resistance to degradation by chemicals to EN 374-4:2013
Resistance of clothing materials to penetration by blood-borne pathogens to ISO 16604:2014

First Issued: 2018-04-26
Latest Issue: 2019-09-12

Effective Date: 2019-09-12
Expiry Date: 2023-04-26

EU Type Examination Certificate

No. CE 688314

Product Specification (Continued)

Model – Nitrile disposable gloves (~~[redacted]~~)

Performance:

General requirements for gloves to EN 420:2003+A1:2009

Dexterity: Level 5

Resistance to penetration to EN 374-2:2014
Pass

Resistance to chemical permeation to EN ISO 374-1:2016
Test method EN 16523-1:2015

n-Heptane (J) – level 1
40% Sodium hydroxide (K) – level 6
96% Sulphuric acid (L) – level 0
37% Formaldehyde (T) – level 5
30% Hydrogen peroxide (P) – level 5

Protection against micro-organism risks to EN ISO 374-5:2016

Bacteria and fungi (Test method EN 374-2:2014) Pass
Viruses (Test Method ISO 16604:2004) Pass

Resistance to degradation by chemicals to EN 374-4:2013

n-Heptane (J) 36.7%
40% Sodium hydroxide (K) -9.0%
96% Sulphuric acid (L) 100%
37% Formaldehyde (T) –39.1%
30% Hydrogen peroxide 40.5%

First Issued: 2018-04-26
Latest Issue: 2019-09-12

Effective Date: 2019-09-12
Expiry Date: 2023-04-26

EU Type Examination Certificate

No. CE 688314

Product Specification (Continued)

Model – Nitrile multipurpose gloves ([redacted])

Performance: **General requirements for gloves to EN 420:2003+A1:2009**

PH Value: Pass

Resistance to chemical permeation to EN ISO 374-1:2016
Test method EN 16523-1:2015

n-Heptane (J) – level 1
40% Sodium hydroxide (K) – level 6
37% Formaldehyde (T) – level 5
30% Hydrogen peroxide (P) – level 4
40% Hydrofluoric acid – level 1

Resistance to penetration by blood borne tested to EN ISO 374-5:2016
Pass

Resistance to degradation by chemicals to EN 374-4:2013

n-Heptane (J) 38.2%
40% Sodium hydroxide (K) –16.3%
37% Formaldehyde (T) 1.3%
30% Hydrogen peroxide (P) 7.1%

First Issued: 2018-04-26
Latest Issue: 2019-09-12

Effective Date: 2019-09-12
Expiry Date: 2023-04-26

EU Type Examination Certificate

No. CE 688314

Certificate Administration Details

Technical File Reference: TF/PPE/002

Certificate Amendment Record

Issue date	Comments	BSI Internal report No.
March 2018	First issue.	0086:18:8888423
December 2018	Addition of models Nitrile Multi-Purpose Gloves	0086:18:9665354
March 2019	Revision to add virus claim.	

Note: The Certificate holder is responsible for keeping the Notified Body advised of changes to any aspect of the overall process used in the manufacture of the product.

Certificate validity
The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The Conformity to Type Based on Quality Assurance of the Production Process, Annex VIII (Module D), for the product are referenced in BSI issued Certificate number CE 51699

First Issued: 2018-04-26
Latest Issue: 2019-09-12

Effective Date: 2019-09-12
Expiry Date: 2023-04-26

EU Type Examination Certificate

No. CE 688314

Location	Certified Activities
[redacted] Malaysia	Powder Free Nitrile Gloves

First Issued: 2018-04-26
Latest Issue: 2019-09-12

Effective Date: 2019-09-12
Expiry Date: 2023-04-26

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

[redacted]
43900
Malaysia

Holds Certificate Number: **MD 99288**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and manufacture of natural rubber and synthetic rubber sterile surgical gloves, sterile and non-sterile examination gloves and sterile urological balloon catheters.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2005-10-21
Effective Date: 2018-01-11
Latest Revision Date: 2018-01-11
Expiry Date: 2020-12-20

UKAS MANAGEMENT SYSTEMS 003

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

[redacted]
Malaysia

Holds Certificate Number: **FM 13934**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design and manufacture of natural rubber and synthetic rubber sterile surgical gloves, sterile and non-sterile examination gloves and sterile urological balloon catheters.

For and on behalf of BSI:

Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 1991-12-03
Latest Revision Date: 2017-11-23

Effective Date: 2017-12-21
Expiry Date: 2020-12-20

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Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	214934	Global Medics Group Pty Ltd - Nitrile examination/treatment glove, non-powdered
ARTG entry for	Medical Device Included Class 1	
Sponsor	Global Medics Group Pty Ltd	
Postal Address	Level 2/371 Spencer Street, MELBOURNE, VIC, 3000 Australia	
ARTG Start Date	23/09/2013	
Product Category	Medical Device Class 1	
Status	Active	
Approval Area	Medical Devices	

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
[redacted]	[redacted] Malaysia

Products

1 . Nitrile examination/treatment glove, non-powdered

Product Type	Single Device Product	Effective Date	23/09/2013
GMDN	56286 Nitrile examination/treatment glove, non-powdered		
Intended Purpose	Nitrile Examination Gloves (Powder Free, Non-sterile) is intended for single use only when conducting dental and medical examination and for handling contaminated medical materials. It is not intended for surgical work.		

Specific Conditions

No Specific Conditions included on Record

Public Summary

Produced at 06.05.2020 at 08:48:40 AEST

This is not an ARTG Certificate document.

The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.

Visit www.tga.gov.au for contact information

Kitemark® Licence

No. KM 13936

BSI hereby grants to:

[redacted]

Malaysia

In respect of:

BS EN 455 Parts 1, 2 & 3:2000

Medical gloves for single use

the right and Licence to use the Kitemark in accordance with the Kitemark Licence Conditions of Contract governing the use of the Kitemark, as may be updated from time to time by BSI, and as approved by the Registrar under the Trade Marks Act 1994 (the "Conditions"). All defined terms in this Licence shall have the same meaning as in the Conditions.

The use of the Kitemark is authorized in respect of the Product(s) detailed on this Licence provided at or from the above address.

For and on behalf of BSI:

Alastair Trivett, Managing Director, BSI Product Services – Global

First granted: **3 Dec 1991** Date: **20 Jul 2007** Page: 1 of 2

UKAS PRODUCT CERTIFICATION 003

The licence remains the property of BSI and shall be returned immediately upon request. This licence does not expire. To check its validity telephone: +44 (0)1442 230442
BSI is incorporated by Royal Charter

BSI Product Services

BSI Product Services
Maylands Avenue, Hemel Hempstead, Hertfordshire HP2 4SQ United Kingdom
Tel: +44 (0)1442 230442 Website: www.bsi-global.com

BSI Group Headquarters 389 Chiswick High Road, London W4 4AL Tel +44 (0)208 996 9000

Kitemark® Licence

No. KM 13936

[redacted]
Malaysia

BS EN 455 Parts 1, 2 & 3:2000 – Medical gloves for single use

Name	Description	Size	Report No.
"Profeel" Powdered	Powdered	5½, 6, 6½, 7, 7½, 8, 8½, 9	BSI Test Reports 186117, & 196274 Refer
"Profeel" Powder Free	No Powder	5½, 6, 6½, 7, 7½, 8, 8½, 9	BSI Test Reports 186117, & 196274 Refer
"Comfit" Powdered	Powdered	5½, 6, 6½, 7, 7½, 8, 8½, 9	BSI Test Reports 186117, & 196274 Refer
"Profeel" Microsurgery Powdered	Brown Powdered	6, 6½, 7, 7½, 8, 8½, 9	BSI Test Report CM001569 Refers
"Profeel" Orthopaedic Powdered	Brown Powdered	5½, 6, 6½, 7, 7½, 8, 8½, 9	BSI Test Report CM001569 Refers
"Profeel" Powder Free	No Powder	5½, 6, 6½, 7, 7½, 8, 8½, 9	BSI Test Report CM001569 Refers
"Profeel" DHD Platinum Powder Free Latex Surgical Gloves	No Powder	5½, 6, 6½, 7, 7½, 8, 8½, 9	251/4416311/1 of 4
"Profeel" DHD Micro Powder Free Latex Surgical Gloves	No Powder	5½, 6, 6½, 7, 7½, 8, 8½, 9	251/4416311/2 of 4
"Profeel" DHD Extra Protection Powder Free Latex Surgical Gloves	No Powder	5½, 6, 6½, 7, 7½, 8, 8½, 9	251/4416311/3 of 4
"Profeel" DHD Synthetic Powder Free Non-Latex Surgical Gloves	No Powder	5½, 6, 6½, 7, 7½, 8, 8½, 9	251/4416311/4 of 4

First granted: **3 Dec 1991**

Date: **20 Jul 2007**

BSI Product Services
Maylands Avenue, Hemel Hempstead, Hertfordshire HP2 4SQ United Kingdom
Tel: +44 (0)1442 230442 Website: www.bsi-global.com
BSI Group Headquarters: 389 Chiswick High Road, London W4 4AL Tel: +44 (0)208 996 9000

EC Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Manufacturer: [redacted]

Address: [redacted] Salak Tinggi,

[redacted]

The undersigned declares that [redacted] as the manufacturer (or its authorised representative established in the EC community) of the product below:

Product Name: Nitrile Examination Gloves Powder free, Non-sterille and sterile

Class: II

Is in conformity with the relevant provision and requirements of directive 93/42/EEC (Annex IX)

Declared by:

P.Gulap

QA Manager

Date : January 2008

./help/index.html)

DRLM Home (mainMenu.htm)

✔ Facility | ✔ Products Listing

Annual Registration Successful

Facility: [redacted] MALAYSIA

You have successfully updated your registration and listing information for 2018.

Your registration will be valid through Dec 31, 2018.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2018.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 8041005.

Facility Information

Registration Number:	**8041005**
Initial Importer:	**N**
Facility Name:	[redacted]
Address:	[redacted]
DUNS Number:	
Foreign Trade Zone:	**N**
Facility URL:	

Other Business Trade Name(s):

Owner/Operator Information

Owner/Operator Number:	8041005
Contact Name:	[redacted]
Company:	[redacted]
Address:	[redacted]
Telephone:	60 - 3870 - 61486
Fax:	-
E-mail:	[redacted]
DUNS Number:	[redacted]

Official Correspondent Information

Contact Name:	SARALA DEVI - JAYARAMAN
Company:	[redacted]
Address:	[redacted]
Telephone:	[redacted]
Fax:	-
E-mail:	[redacted]
DUNS Number:	

United States Agent Information

Contact Name:	Micheal Scaglione
Contact Title:	Mr
Business Name:	[redacted]
Address:	3700 Massillon rd Uniontown, Ohio, 44685, UNITED STATES
Phone:	330 - 8961066
Fax:	
DUNS Number:	

E-mail: [redacted]

JUL 0 5 2002

[redacted]
147817V

K021119

510 (K) SUMMARY OF POWDERED BROWN LATEX SURGICAL GLOVES, STERILE

The device in this 510(k) submission is the Powdered Brown Latex Surgical Gloves, Sterile which is made of natural rubber latex. These gloves are intended to be worn by surgeons and/or operating room personnel to protect a surgical wound from contamination.

The Powdered Brown Latex Surgical Gloves, Sterile are substantially equivalent to Microptic, Brown Beaded Surgeon's Gloves (Powdered, Hypoallergenic) submitted and cleared under 510(k) number K960416. The only difference in this submission is to include the Expiration Date Labeling Claim and Protein Content Labeling Claim with no changes in product design. The results of stability study and protein content test conducted on Powdered Brown Latex Surgical Gloves, Sterile are submitted to support the expiration date labeling claim and protein content labeling claim.

Based on the results obtained through out the Stability Test, it can be concluded that the Powdered Brown Latex Surgical Gloves, Sterile produced by WRP Asia Pacific Sdn Bhd has demonstrated that the barrier properties, physical and mechanical properties, packaging integrity and sterility of the gloves are maintained for the duration of the claimed shelf-life (expiration date, i.e. 5 years). Also, based on the protein content test report, the protein level of the gloves is well below 50 μg/g and supports our protein content labeling claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. K. K Leong
Associate Manager, QA/RA
[redacted]
MALAYSIA

JUL 5 - 2002

Re: K021119
Trade/Device Name: Powdered Brown Latex Surgical Gloves, Sterile with Expiration Date Labeling Claim and Protein Content Labeling Claim
Regulation Number: 878.4460
Regulation Name: Surgical Gloves
Regulatory Class: I
Product Code: KGO
Dated: April 4, 2002
Received: April 8, 2002

Dear Mr. Leong:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

[redacted]

147817V

INDICATIONS FOR USE

Applicant: [redacted]

510(k) Number (if known): K021119

Device Name: POWDERED BROWN LATEX SURGICAL GLOVES, STERILE WITH EXPIRATION DATE LABELING CLAIM AND PROTEIN CONTENT LABELING CLAIM

Indications For Use:

The surgical glove is a device made of natural rubber latex intended to be worn by surgeons and/or operating room personnel to protect a surgical wound from contamination.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021119

Prescription Use _____ OR Over-The-Counter _____
(Per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. K. K. Leong
Associate manager, QA/RA
[redacted]
MALAYSIA

Re: K021119 (Powdered Brown Latex Surgical Gloves, Sterile with Expiration Date Labeling Claim)
K021159 (Powdered Latex Surgical Gloves, Sterile with Expiration Date Labeling Claim)

Dear Mr. Leong:

This letter notifies you that the data you submitted in your 510(k) submissions for the Powdered Brown latex Surgical Glove, Sterile with Expiration Date labeling Claim (K021119) and Powdered Latex Surgical Gloves, Sterile with expiration Date Labeling Claim (K021159) are inadequate to support a 5 year shelf life. Although FDA has determined that both 510(k)s are substantial equivalent, the shelf life labeling claim is a quality systems issue, not a premarket issue.

If you include a 5- year shelf life on your products with the data in the 510(k) submissions, FDA will consider your products misbranded.

If you wish to add a 5- year shelf life to the products labeling, please revise the test protocol you intend to use for the study, which should take FDA's July 5, 2002, comments into consideration. Please advise FDA of your intentions no later than July 31, 2002. If you have any questions, please contact Chiu Lin, Ph.D., Branch Chief, Infection Control Devices Branch at 301-443-8913.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

No. Siri: 002576
Serial No.:

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN

MEDICAL DEVICE
AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
LESEN ESTABLISMEN
ESTABLISHMENT LICENCE
Seksyen 24(1) Akta 737
Section 24(1) of Act 737

No. Lesen: **MDA-217-K12415**
Licence No.:

Tarikh Sah Lesen: **01/07/2018 - 30/06/2021**
Licence Validity Date:

Lesen adalah dengan ini diberi kepada:
Licence is hereby granted to:

[redacted]

yang beralamat di:
of

[redacted]

Sebagai:
as

PEMBUAT
MANUFACTURER

Orang yang bertanggungjawab:
Person Responsible

DATO' LEE SON HONG (I/C NO. : 570226-08-5145)

Lesen ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan dibawahnya serta syarat-syarat seperti di Lampiran 1.
This licence is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 1.

ZAMANE BIN ABDUL RAHMAN
Ketua Eksekutif
Chief Executive
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY