
240mm (9 1/2")
300mm (12")
330mm (13")
355mm (14")
400mm (16")
480mm (19")
530mm (21")
600mm (24")
SERVICE
EXCELLENCE
INNOVATION
QUALITY
FingerFlex Technology
Glove for Comfort & Dexterity
(A Patented Glove)
FingerFlex®
TECHNOLOGY
Brightway Holding
(169521-T)
Manufacturer and Global Distributor of various types and lengths o
Examination, Industrial and Critical Environment Gloves

The Company

Brightway Group comprises of Brightway Holdings Sdn. Bhd. as its Corporate and Administrative Centre, Laglove (M) Sdn. Bhd. and Biopro (M) Sdn. Bhd. as its main production facilities. The group has a total of 41 lines and is capable of producing 230 million gloves per month. With a total workforce of 2500 people, Product Innovation & Process Improvements are our key to satisfy customer needs and maintain our status as a Premier and Niche Market Glove Manufacturer.

Brightway Holdings Sdn. Bhd.

Incorporated in 1988, Brightway Holdings produces a full range of natural and synthetic gloves and markets globally for the medical, industrial and cleanroom applications. Brightway, which commenced its manufacturing operations with 4 production lines in 1991 is located at Batu Belah, Klang which is close to Port Klang. In addition, it has its 2nd Factory at Bestari Jaya (Batang Berjuntai) and the 3rd Factory at Chemor, Perak. These three factories have a cumulative production of 70 million gloves per month, mostly of the specialty types with a support of 900 employees. Brightway is the group administrative, testing and research & development centre. Our strength is in our ability to meet customer specifications and provide a wide range of products in line with the quality requirements & market demands of our customers.

Laglove (M) Sdn. Bhd.

Incorporated in 1991, located in Kajang, Selangor Laglove has 9 production lines with an output of 47 million pieces per month, producing mostly Cleanroom and EMS (mostly UL / NFPA certified) gloves in Nitrile and Natural Latex. Nitrile Sheaths and shoe covers are also produced in this facility.

Biopro (M) Sdn. Bhd.

Biopro started operating in 1988. It houses 17 production lines, inclusive of 7 state-of-the-art double former lines with an output of 113 million pieces per month. Located at Kawasan Perindustrian Sultan Hishamuddin, Port Klang, Selangor ; it is also equipped to 'slip sheet', pack and load containers.

Brightway Cleanroom

Brightway takes pride in its state of the art Cleanroom facility that is capable of processing Latex & Nitrile gloves to Class 100 and Class 10. The Cleanroom is equipped with RO-DI Water System which is able to produce consistent high purity DI water of 18 mega ohms. The raised flooring and the UEPA filters ensures that Class 10 standards are achieved within the Cleanroom. All gloves processed within the Cleanroom are tested for Non-Volatile Residue, Liquid Particle Count is tested using the 0.5 micron (μ) particle counter. An-ions & Cat-ions are tested with the Ion Chromatograph machine and Zinc Content, using a Spectrophotometer

Laboratory Testing

Within our facilities, we are able to conduct Protein Test, Aging Test, Tensile Test, Powder Content Test, Shear Stress Test and MST. These tests are carried out by our trained QA personnel to ensure that the products leaving the factory meets the standards and customer requirements.

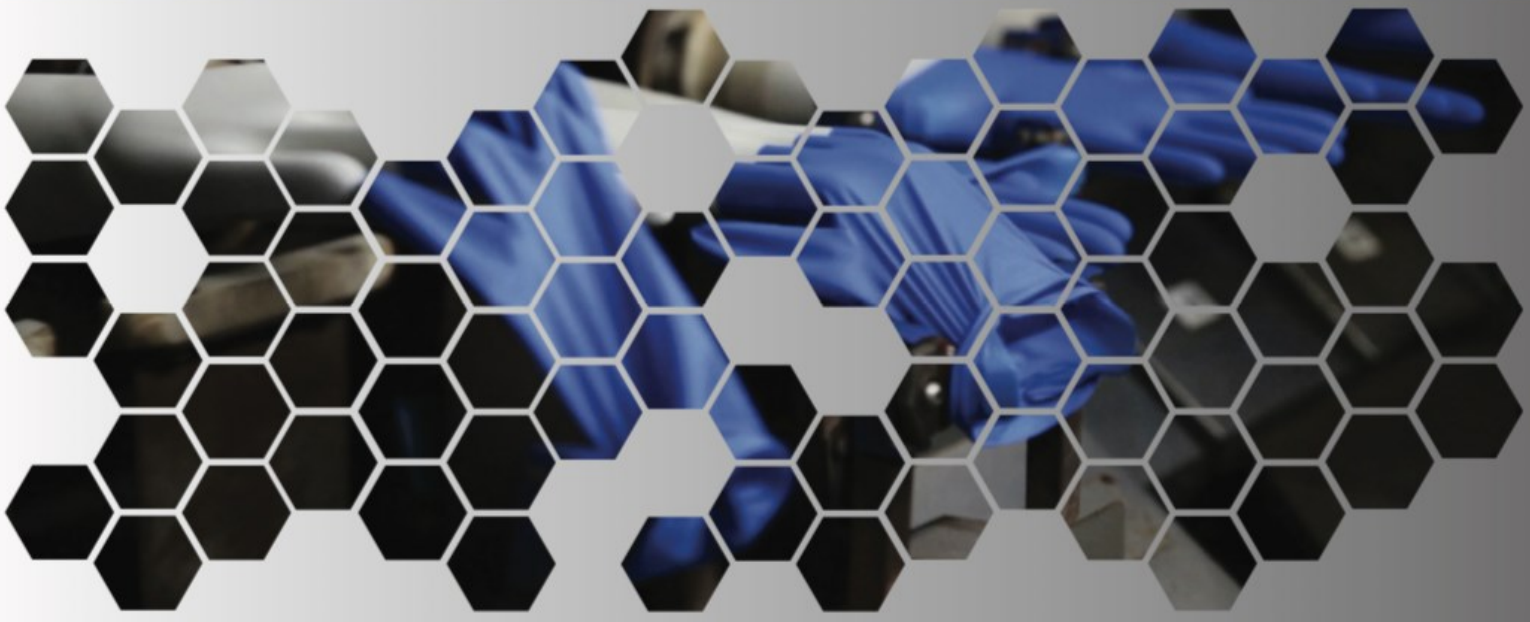
Fingerflex Technology®

Fingerflex Technology® offers a great breakthrough in comfort. We have done various tests on users who have found the Fingerflex gloves to be more comfortable to work with. This is another example of our quest to satisfy our customers with continuous improvement.

Other Innovations

Nitrile Sheath for Female Condom, Latex Shoe Covers, Chemical Gloves, Gauntlets and Chicken Deboning Gloves are our latest additions.

Brightway®



Examination Gloves

AMBIDEXTROUS — NON-STERILE — DISPOSABLE

Examination gloves you rely on during diagnosis, handling instruments and medical procedures.

The perfect way to prevent infection from patients with contagious diseases through their boldy fluids or physical contact.

- ISO 9002 followed in production
- Proven and tested safe against dermal sensitization
- Confirms to ASTMD D 3578 Quality Standards
- FDA approved

Latex Examination Gloves - Powder Free / Powdered

Nitrile Examination Gloves - Powder Free / Powdered

LATEX GLOVES

Manufactured in accordance to the highest quality standards that ensures dexterity, protection and comfort. These gloves are produced using 100% natural latex. We produce both Ambidextrous and Hand Specific gloves that are low in protein content which are then processed for Medical, Industrial and Cleanroom use. Gloves range from 6mil to 20mil in thickness and are mostly produced to customer specification (OEM).

Design and Features

Smooth	Online Powder Free Gloves
Textured	Offline Double Chlorinated Gloves
Finger Textured	Polymer Coated Gloves
Finger Flex Technology	Tapered and Beaded Cuff

Length
240mm (9 ½") | 300mm (12") | 330mm (13") | 355mm (14") | 400mm (16") | 480mm (19") | 530mm (21") | 600mm (24")

Sizes
Ambidextrous: XXS , XS, S, M, L, XL, XXL, XXXL
Hand Specific: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 10.0

Color
Natural, Blue, Green, Black, Brown, Orange

Packing
Non-Sterile Gloves
- Packed in dispenser boxes and into a shipper carton

Sterile Gloves
- Walleted using PE or Paper, pouched and packed in a dispenser and into a shipper carton

Cleanroom Gloves
- Packed in double polybags for non sterile and sterile gloves are walleted in Cleanroom HDPE wallets, placed in Cleanroom Plastic Pouches and in a lined shipper carton. Packed in either our in-house brand or OEM.

(We can accommodate to customer Branding — OEM)

QA Standard
Full traceability using QMS techniques
Inspection Levels:
- Barrier defect: G1, AQL 0.65 | G1, AQL 1.0 | G1, AQL 1.5
- Major defect: G1, AQL 2.5
- Minor defect: G1, AQL 4.0

Sterilization
Gamma Irradiation or EO sterilized

Applications
Chemo Drug Handling, EMS Personnel, Medical, Industrial, Laboratory, Clean Room, OBS and Gynae

Cleanroom Latex Gloves
The gloves are processed to better than standard, in respect of its properties, particulates and extractable which are kept at a minimal level to ensure that the gloves are as per specifications issued by our customers from many different sectors. These gloves are commonly used in the semi conductor, electronic and pharmaceutical industries and laboratories.

Our Standard Cleanroom Specifications
The gloves are processed to better than standard, in respect of its properties, particulates and extractable.

Powder Free Latex Gloves - Clean Room Use Specifications - Class 10									
Particle Count (IES - RP - C005.2)	Ionic Burden (mg/cm²)							Non-Volatile Residue (DI Water Extraction)	Silicon Oil Presence by FTIR (Hexane Extraction)
	Anions			Cations					
Count per cm²	Cl^-	NO_3^{2-}	SO_4^{2-}	Ca^{2+}	Mg^{2+}	K^+	Na^{2+}	(mg/cm²)	ABSENT
< 700	< 0.25	< 0.20	< 0.05	< 0.2	< 0.005	< 0.03	< 0.02	< 6	

Powder Free Latex Gloves - Clean Room Use Specifications - Class 100									
Particle Count (IES - RP - C005.2)	Ionic Burden (mg/cm²)							Non-Volatile Residue (DI Water Extraction)	Silicon Oil Presence by FTIR (Hexane Extraction)
	Anions			Cations					
Count per cm²	Cl^-	NO_3^{2-}	SO_4^{2-}	Ca^{2+}	Mg^{2+}	K^+	Na^{2+}	(mg/cm²)	ABSENT
< 1,200	< 0.75	< 0.4	< 0.1	< 0.4	< 0.01	< 0.05	< 0.04	< 10	

NITRILE GLOVES

Manufactured in accordance to the highest quality standards — ASTM D 3577 for Surgical Gloves and ASTM D 6319 for Examination Gloves that ensures dexterity, protection and comfort. These gloves are produced using 100% Acrylonitrile Butadiene Latex. We produce both Ambidextrous and Hand Specific gloves that are low in protein content which are then processed for Medical, Industrial and Cleanroom use. Gloves range from 6mil to 20mil in thickness and are mostly produced to customer specification (OEM).

Design and Features

Smooth
Textured
Finger Textured
Finger Flex Technology
Chemical Gloves
Tri-polymer Gloves
Online Powder Free Gloves
Offline Double Chlorinated Gloves
Polymer Coated Gloves
Tapered and Beaded Cuff
Neophrene Gloves

Length

240mm (9 ½") | 300mm (12") | 330mm (13") | 355mm (14") | 400mm (16") | 480mm (19") | 530mm (21") | 600mm (24")

Sizes

Ambidextrous: XXS , XS, S, M, L, XL, XXL, XXXL
Hand Specific: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 10.0

Color

Natural, Blue, Green, Black, Brown, Orange, Blurple

Packing

Non-Sterile Gloves
- Packed in dispenser boxes and into a shipper carton

Sterile Gloves
- Walleted using PE or Paper, pouched and packed in a dispenser and into a shipper carton

Cleanroom Gloves
- Packed in double polybags for non sterile and sterile gloves are walleted in Cleanroom HDPE wallets, placed in Cleanroom Plastic Pouches and in a lined shipper carton. Packed in either our in-house brand or OEM.

(We can accommodate to customer Branding — OEM)

QA Standard

Full traceability using QMS techniques
Inspection Levels:
- Barrier defect: G1, AQL 0.65 | G1, AQL 1.0 | G1, AQL 1.5
- Major defect: G1, AQL 2.5
- Minor defect: G1, AQL 4.0

Sterilization

Gamma Irradiation or EO sterilized

Applications

Chemo Drug Handling, EMS Personnel, Medical, Industrial, Laboratory, Clean Room, OBS and Gynae

Cleanroom Latex Gloves

The gloves are processed to better than standard, in respect of its properties, particulates and extractable which are kept at a minimal level to ensure that the gloves are as per specifications issued by our customers from many different sectors. These gloves are commonly used in the semi conductor, electronic and pharmaceutical industries and laboratories.

Our Standard Cleanroom Specifications

The gloves are processed to better than standard, in respect of its properties, particulates and extractable.

Powder Free Nitrile Gloves - Clean Room Use Specifications - Class 10									
Particle Count (IES - RP - C005.2)	Ionic Burden (mg/cm²)							Non-Volatile Residue (DI Water Extraction)	Silicon Oil Presence by FTIR (Hexane Extraction)
	Anions			Cations					
Count per cm²	Cl^-	NO_3^{2-}	SO_4^{2-}	Ca^{2+}	Mg^{2+}	K^+	Na^{2+}	(mg/cm²)	ABSENT
< 700	< 0.25	< 0.15	< 0.02	< 0.1	< 0.005	< 0.03	< 0.02	< 6	

Powder Free Nitrile Gloves - Clean Room Use Specifications - Class 100									
Particle Count (IES - RP - C005.2)	Ionic Burden (mg/cm²)							Non-Volatile Residue (DI Water Extraction)	Silicon Oil Presence by FTIR (Hexane Extraction)
	Anions			Cations					
Count per cm²	Cl^-	NO_3^{2-}	SO_4^{2-}	Ca^{2+}	Mg^{2+}	K^+	Na^{2+}	(mg/cm²)	ABSENT
< 1,200	< 0.15	< 0.2	< 0.05	< 0.2	< 0.05	< 0.05	< 0.05	< 10	

FDA Home[3] Medical Devices[4] Databases[5]

510(k) Premarket Notification

6510(k)[7] |DeNovo[8]|Registration & Listing[9] |Adverse Events[10] |Recalls[11]|PMA[12]|HDE[13]|Classification[14]|Standards[15]
CFR Title 21[16]|Radiation-Emitting Products[17] |X-Ray Assembler[18]|Medsun Reports[19]|CLIA[20]|TPLC[21]

New Search Back To Search Results

Device Classification Name	Latex Patient Examination Glove[22]
510(K) Number	K990539
Device Name	BRIGHTWAY BRAND LATEX EXAMINATION GLOVES (POWDER FREE)
Applicant	BRIGHTWAY HOLDINGS SDN. BHD. LOT 1559, JALAN ISTIMEWA, BATU BELAH Klang, Selangor, MY 42100
Applicant Contact	G. Baskaran
Correspondent	BRIGHTWAY HOLDINGS SDN. BHD. LOT 1559, JALAN ISTIMEWA, BATU BELAH Klang, Selangor, MY 42100
Correspondent Contact	G. Baskaran
Regulation Number	880.6250[23]
Classification Product Code	LYY[24]
Date Received	02/22/1999
Decision Date	04/09/1999
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Statement	Statement[25]
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm

Certificate MY00/51712

The management system of

Brightway Holdings Sdn. Bhd.
Laglove (M) Sdn. Bhd.
Biopro (M) Sdn. Bhd.

Lot 1559, Jalan Istimewa, Bt. Belah
42100 Klang, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

Manufacture of Natural (Latex) and Synthetic Latex (Nitrile) Examination, Surgical and Industrial Gloves & Nitrile Sheath.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 19 February 2016 until 14 September 2018 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 August 2018
Issue 8. Certified since 07 July 2000

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

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

UKAS MANAGEMENT SYSTEMS
0005

SGS 9001-8 01 0614 M2

Certificate MY00/51712

The management system of

Brightway Holdings Sdn. Bhd.
Laglove (M) Sdn. Bhd.
Biopro (M) Sdn. Bhd.

Lot 1559, Jalan Istimewa, Bt. Belah
42100 Klang, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

ISO 9001:2008

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t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

UKAS MANAGEMENT SYSTEMS
0005

SGS 9001-8 01 0614 M2

Certificate MY00/51711

The management system of

Brightway Holdings Sdn. Bhd. also trading as Laglove (M) Sdn. Bhd. and Biopro (M) Sdn. Bhd.

Lot 1559, Jalan Istimewa, Bt. Belah,
42100 Klang, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 02 April 2019 until 19 February 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 19 December 2021
Issue 12. Certified since 07 July 2000

Expiry date of last certificate: 19 February 2019
End date of last recertification audit: 30 November 2018

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

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 13485 2016 0118 M2

Brightway Holdings Sdn. Bhd. also trading as Laglove (M) Sdn. Bhd. and Biopro (M) Sdn. Bhd.

ISO 13485:2016
EN ISO 13485:2016

Issue 12

Detailed scope

Manufacture of Non Sterile Natural (Latex) and Synthetic Latex (Nitrile) Examination & Sterile Surgical Gloves.

Additional facilities

Laglove (M) Sdn. Bhd.
Lot 478, Jalan Simpang Balak, Off Batu 13
Jalan Cheras, 43000 Kajang, Selangor Darul Ehsan
MALAYSIA

Biopro (M) Sdn. Bhd.
Lot 14, PT 4204 Lingkaran Sultan Hishamuddin
North Port Industrial Estate
42000 Port Klang, Selangor Darul Ehsan
MALAYSIA

UKAS MANAGEMENT SYSTEMS
0005

Certificate MY00/51711

The management system of

Brightway Holdings Sdn. Bhd. also trading as Laglove (M) Sdn. Bhd. and Biopro (M) Sdn. Bhd.

Lot 1559, Jalan Istimewa, Bt. Belah,
42100 Klang, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

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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 13485 2016 0118 M2

Brightway Holdings Sdn. Bhd. also trading as Laglove (M) Sdn. Bhd. and Biopro (M) Sdn. Bhd.

ISO 13485:2016
EN ISO 13485:2016

Issue 12

Detailed scope

Manufacture of Non Sterile Natural (Latex) and Synthetic Latex (Nitrile) Examination & Sterile Surgical Gloves.

Additional facilities

Laglove (M) Sdn. Bhd.
Lot 478, Jalan Simpang Balak, Off Batu 13
Jalan Cheras, 43000 Kajang, Selangor Darul Ehsan
MALAYSIA

Biopro (M) Sdn. Bhd.
Lot 14, PT 4204 Lingkaran Sultan Hishamuddin
North Port Industrial Estate
42000 Port Klang, Selangor Darul Ehsan
MALAYSIA

UKAS MANAGEMENT SYSTEMS
0005

EC Certificate Production Quality Assurance System: Certificate MY00/51710.00

The management system of

Brightway Holdings Sdn. Bhd.

Lot 1559, Jalan Istimewa, Bt. Belah
42100 Klang, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Sterile Natural (Latex) and Synthetic Latex (Nitrile) Surgical Gloves.

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 19 February 2016 until 19 February 2021 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 19 December 2018
Issue 8. Certified since 07 July 2000

Certification is based on reports numbered MY/KUL MY00370

Multiple certificates have been issued for this scope
The main certificate is numbered MY00/51710.00

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 14 0215

EC Certificate Production Quality Assurance System: Certificate MY00/51710.01

The management system of

Laglove (M) Sdn. Bhd.

Lot 478, Jalan Simpang Balak, Off Batu 13, Jalan Cheras
43000 Kajang, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Sterile Natural (Latex) and Synthetic Latex (Nitrile) Surgical Gloves.

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 19 February 2016 until 19 February 2021 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 19 December 2018
Issue 5. Certified since 04 August 2004

Certification is based on reports numbered MY/KUL MY00370

Multiple certificates have been issued for this scope
The main certificate is numbered MY00/51710.00

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 14 0215

EC Certificate Production Quality Assurance System: Certificate MY00/51710.02

The management system of

Biopro (M) Sdn. Bhd.

Lot 14, PT 4204 Lingkaran Sultan Hishamuddin
North Port Industrial Estate, 42000 Port Klang
Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Sterile Natural (Latex) and Synthetic Latex (Nitrile) Surgical Gloves.

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 19 February 2016 until 19 February 2021 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 19 December 2018
Issue 5. Certified since 04 August 2004

Certification is based on reports numbered MY/KUL MY00370

Multiple certificates have been issued for this scope
The main certificate is numbered MY00/51710.00

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 14 0215

CANADIAN GENERAL STANDARDS BOARD

Certificate of Listing

This is to Certify that

Bright Way Holdings Sdn. Bhd.

Lot 1559. Jalan Istimewa, Batu Belah, 42100 Klang, Selangor Darul Ehsan Malaysia

has met the requirements of the CGSB *Certification Listing Program for Medical Gloves Program*

This certificate covers only items on the Certification Program List

Director

Date of Listing 2002/02/27

Canada

NEXTECH

CERTIFICATE OF COMPLIANCE

BRIGHTWAY HOLDINGS SDN. BHD.

Cuffing & Walleting	*(ISO Class 5)*
Washers & Drayers	*(ISO Class 5)*
Staging Area/ Pouching	*(ISO Class 5)*
Gowning Room	*(ISO Class 7)*
Lab	*(ISO Class 7)*

Test Condition : At Rest

As per requirement of ISO 14644 the designated area listed have met the respective acceptance criteria. Testing was performed as outlined in the above standard and the results are attested to it in the

Report No: 315/CR~10/2018

Nextech Sdn Bhd
NEBB
TAN CHEE KIAN
CERTIFICATION
3144
Exp 31/03/20
Cleanroom Performance Testing

Date of Certification : 05/10/2018
Due Date : 05/10/2019

Alvin Tan Chee Kian
CPT Certified Professional

NEXTECH SDN. BHD.
19, Jalan Bukit Bandung 26/4, HICOM Industrial Estate
40000 Shah Alam, Selangor Darul Ehsan, Malaysia.
Tel: 03-51923833 Fax : 03-51922088

Certificate MY19/1811029965

The management system of

Brightway Holdings Sdn. Bhd. also Trading as Laglove (M) Sdn. Bhd. and Biopro (M) Sdn. Bhd.

Site 1 – Plant 1
Lot 1559, Jalan Istimewa, Bt. Belah
42100 Klang, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

Module D

For the following activities

Manufacture of Chemical Protective Latex and Nitrile Gloves.
Note: All products marked CE0598 must have a valid EU type-examination certificate issued under Module B or a valid EC type-examination certificate issued under Article 10 of the PPE Directive 89/686/EEC.

This certificate is valid from 17 April 2019 until 19 February 2022 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 19 December 2021
Issue 2. Certified since 25 March 2019

This is a multi-site certification.
Additional site details are listed on the subsequent page.

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Authorised by

SGS FIMKO OY, Notified Body 0598
P.O. Box 30 (Särkiniementie 3),00211 Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

Brightway Holdings Sdn. Bhd. also Trading as Laglove (M) Sdn. Bhd. and Biopro (M) Sdn. Bhd.

Regulation (EU) 2016/425

Module D

Issue 2

Detailed scope

Manufacture of Chemical Protective Latex and Nitrile Gloves.
Note: All products marked CE0598 must have a valid EU type-examination certificate issued under Module B or a valid EC type-examination certificate issued under Article 10 of the PPE Directive 89/686/EEC.

Additional facilities

Site 1 – Plant 2
PT 4250 & PT 4251, Solok Sultan Hishamuddin 7, Kaw. 20
Pelabuhan Klang Utara K/U 17, 42100 Klang, Selangor Darul Ehsan
MALAYSIA

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Site 2
Lot 478, Jalan Simpang Balak, Off Batu 13
Jalan Cheras, 43000 Kajang, Selangor Darul Ehsan
MALAYSIA

Site 3
Lot 14, PT 4204 Lingkaran Sultan Hishamuddin
North Port Industrial Estate
42000 Port Klang, Selangor Darul Ehsan
MALAYSIA

Certificate MY19/1811029965

The management system of

Brightway Holdings Sdn. Bhd. also Trading as Laglove (M) Sdn. Bhd. and Biopro (M) Sdn. Bhd.

Site 1 – Plant 1
Lot 1559, Jalan Istimewa, Bt. Belah
42100 Klang, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

Module D

For the following activities

Manufacture of Chemical Protective Latex and Nitrile Gloves. Note: All products marked CE0120 must have a valid EU type-examination certificate issued under Module B or a valid EC type-examination certificate issued under Article 10 of the PPE Directive 89/686/EEC.

This certificate is valid from 25 March 2019 until 19 February 2022 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 19 December 2021
Issue 1. Certified since 25 March 2019

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

UKAS PRODUCT CERTIFICATION
0005

SGS United Kingdom Limited, Notified Body 0120
Unit 202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

HC SGS 2016/425 D 0118 M2

Brightway Holdings Sdn. Bhd. also Trading as Laglove (M) Sdn. Bhd. and Biopro (M) Sdn. Bhd.

Regulation (EU) 2016/425

Module D

Issue 1

Detailed scope

Manufacture of Chemical Protective Latex and Nitrile Gloves.
Note: All products marked CE0120 must have a valid EU type-examination certificate issued under Module B or a valid EC type-examination certificate issued under Article 10 of the PPE Directive 89/686/EEC.

Additional facilities

Site 1 – Plant 2
PT 4250 & PT 4251, Solok Sultan Hishamuddin 7, Kaw. 20
Pelabuhan Klang Utara K/U 17, 42100 Klang, Selangor Darul Ehsan
MALAYSIA

Site 2
Lot 478, Jalan Simpang Balak, Off Batu 13
Jalan Cheras, 43000 Kajang, Selangor Darul Ehsan
MALAYSIA

Site 3
Lot 14, PT 4204 Lingkaran Sultan Hishamuddin
North Port Industrial Estate
42000 Port Klang, Selangor Darul Ehsan
MALAYSIA

UKAS PRODUCT CERTIFICATION
0005

No. Siri:
Serial No.: **024094**

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)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **GMD59378860018A**
Registration No.:

Tarikh Sah Laku Pendaftaran: **09/11/2018 - 08/11/2023**
Registration Validity Date:

Sijil ini adalah dengan ini dikeluarkan kepada:
This Certificate is hereby issued to:

BRIGHT WAY HOLDINGS SDN. BHD.

yang beralamat di:
of:

LOT 1559 JALAN ISTIMEWA, BATU BELAH,
42100 KLANG, SELANGOR, MALAYSIA
42100 SELANGOR

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.
to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.
This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.

AHMAD SHARIFF BIN HAMBALI
Ketua Eksekutif
Chief Executive
Pihak Berkuasa Peranti Perubatan
Medical Device Authority

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **GMD59378860018A**
Registration No.:

Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan *Medical Device Name*	**POWDER FREE NITRILE EXAMINATION GLOVE**		
Kelas *Class*	**CLASS A**	Brand *Brand*	**BRIGHTWAY POWDER FREE EXAMINATION GLOVE (NITRILE)**
Kelompok *Group*	**SINGLE**	Produk Identifikasi *Product Identifier*	**NOT APPLICABLE**
Kegunaan Yang Diniatkan *Intended Use*	**Nitrile Examination gloves is a disposable device intended for medical purpose is worn on the examiner's or medical practiser's hand to prevent contamination between patient and examiner. The device is for over-the-counter use.**		
Nama dan alamat pembuat: *Name and address of manufacturer*	**LOT 1559 JALAN ISTIMEWA, BATU BELAH, 42100 KLANG, SELANGOR, MALAYSIA 42100 SELANGOR**		

No. Siri:
Serial No.: **024093**

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)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **GMD95088860118A**
Registration No.:

Tarikh Sah Laku Pendaftaran: **09/11/2018 - 08/11/2023**
Registration Validity Date:

Sijil ini adalah dengan ini dikeluarkan kepada:
This Certificate is hereby issued to:

BRIGHT WAY HOLDINGS SDN. BHD.

yang beralamat di:
of:

LOT 1559 JALAN ISTIMEWA, BATU BELAH,
42100 KLANG, SELANGOR, MALAYSIA
42100 SELANGOR

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.
to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.
This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.

AHMAD SHARIFF BIN HAMBALI
Ketua Eksekutif
Chief Executive
Pihak Berkuasa Peranti Perubatan
Medical Device Authority

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **GMD950888860118A**
Registration No.:

Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan *Medical Device Name*	**POWDER FREE LATEX EXAMINATION GLOVE**		
Kelas *Class*	**CLASS A**	Brand *Brand*	**BRIGHTWAY POWDER FREE LATEX EXAMINATION GLOVE (LATEX)**
Kelompok *Group*	**FAMILY**		
Kegunaan Yang Diniatkan *Intended Use*	**Latex Examination gloves is a disposable device intended for medical purpose is worn on the examiner's or medical practiser's hand to prevent contamination between patient and examiner. The device is for over-the-counter use.**		
Nama dan alamat pembuat: *Name and address of manufacturer*	**LOT 1559 JALAN ISTIMEWA, BATU BELAH, 42100 KLANG, SELANGOR, MALAYSIA 42100 SELANGOR**		

APPENDIX

No.	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1.	Latex Examination Glove	Size L	Palm Width 106mm
2.	Latex Examination Glove	Size XL	Palm Width 112mm
3.	Latex Examination Glove	Size XXL	Palm Width 118mm
4.	Latex Examination Glove	Size XXXL	Palm Width 122mm
5.	Latex Examination Glove	Size M	Palm Width 95mm
6.	Latex Examination Glove	Size XS	Palm Width 77mm
7.	Latex Examination Glove	Size S	Palm Width 83mm

No. Siri: 002028
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 15(1) Akta 737
Section 15(1) of Act 737

No. Lesen: **KP76989168617**
License No.:

Tarikh Sah Lesen: **04/04/2017**
License Validity Date: **03/04/2020**

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

BRIGHT WAY HOLDINGS SDN. BHD.

yang beralamat di:
of
LOT 1559 JALAN ISTIMEWA, BATU BELAH,
42100 KLANG, SELANGOR, MALAYSIA
42100 SELANGOR

Sebagai:
as
PEMBUAT
MANUFACTURER

Orang yang bertanggungjawab: **DR. BASKARAN GOVINDASAMY (I/C: 530309085953)**
Person Responsible:

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

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Brightway Holdings Sdn. Bhd.
Site 1 (Plant 1)
Lot 1559, Jalan Istimewa,
Bt. Belah,
Klang
Selangor
42100
Malaysia

DUNS Number: 89-425-3152

Holds Certificate No: **MDSAP 704971**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and Manufacturing of Non Sterile Natural (Latex), Synthetic Latex (Nitrile) Examination and Sterile Surgical Gloves.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-08-02 Effective Date: 2019-08-02 Expiry Date: 2022-08-01

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

Certificate No: **MDSAP 704971**

Location	Registered Activities
Brightway Holdings Sdn. Bhd. Site 1 (Plant 1) Lot 1559, Jalan Istimewa, Bt. Belah, Klang Selangor 42100 Malaysia DUNS Number: 89-425-3152	Manufacturing of Non Sterile Natural (Latex), Synthetic Latex (Nitrile) Examination and Sterile Surgical Gloves.
Brightway Holdings Sdn. Bhd. Site 1 (Plant 2) PT 4250 & PT 4251, Solok Sultan Hishamuddin 7, Kaw. 20, Pelabuhan Klang Utara K/U 17, Klang Selangor 42100 Malaysia	Manufacturing of Non Sterile Natural (Latex), Synthetic Latex (Nitrile) Examination and Sterile Surgical Gloves.
Biopro (M) Sdn. Bhd Site 3 Lot 14, PT 4204 Lingkaran Sultan Hishamuddin, North Port Industrial Estate, Port Klang Selangor 42000 Malaysia	Design and Manufacturing of Non Sterile Natural (Latex), Synthetic Latex (Nitrile) Examination and Sterile Surgical Gloves.
Laglove (M) Sdn. Bhd Site 2 Lot 478, Jalan Simpang Balak, Off Batu 13, Jalan Cheras, Kajang 43000 Malaysia	Manufacturing of Non Sterile Natural (Latex), Synthetic Latex (Nitrile) Examination and Sterile Surgical Gloves.

Original Registration Date: 2019-08-02 Effective Date: 2019-08-02 Expiry Date: 2022-08-01

Bright way: 230 x 260 x 260
Net :5kg
Gross: 5.47kg