

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 3mil to 15mil in thickness and are mostly produced to customer specification (OEM).

Design & 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 & Beaded Cuff
- Neoprene 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, Blue

Packing :

- Non-Sterile Gloves
- Packed in dispenser boxes and into a shipper carton
- Sterile Gloves
- Walletted using PE or Paper, pouched & packed in a dispenser and into a shipper carton
- Cleanroom Gloves
- Packed in double polybags for non sterile and sterile gloves are walletted 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 & Gynae

Cleanroom Nitrile Gloves

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

Powder Free Nitrile Gloves - Clean Room Use Specifications - Class 10									
Particle Count (IES - RP - C005.2)	Ionic Burden (mg/ cm ²)							Non-Volatile Residue (DI Water Extraction) (mg/ cm ²)	Silicon Oil Presence:by FTIR (Hexane Extraction)
	Anions			Cations					
Count per cm ²	Cl ⁻	NO ₃ ²⁻	SO ₄ ²⁻	Ca ²⁺	Mg ²⁺	K ⁺	Na ²⁺		
< 700	< 0.25	< 0.15	< 0.02	< 0.1	< 0.005	< 0.03	< 0.02	< 6	ABSENT

Powder Free Latex Gloves - C Clean Room Use Specifications - Class 100									
Particle Count (IES - RP - C005.2)	Ionic Burden (mg/ cm ²)							Non-Volatile Residue (DI Water Extraction) (mg/ cm ²)	Silicon Oil Presence:by FTIR (Hexane Extraction)
	Anions			Cations					
Count per cm ²	Cl ⁻	NO ₃ ²⁻	SO ₄ ²⁻	Ca ²⁺	Mg ²⁺	K ⁺	Na ²⁺		
< 1,200	< 0.15	< 0.20	< 0.05	< 0.2	< 0.05	< 0.05	< 0.05	< 10	ABSENT

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 & Features :

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

Length :

- 240mm (9 1/2 ") • 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
 - Walleled using PE or Paper, pouched & packed in a dispenser and into a shipper carton
- Cleanroom Gloves
 - Packed in double polybags for non sterile and sterile gloves are walleled 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 & 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

Powder Free Latex Gloves - Clean Room Use Specifications - Class 10

Particle Count (IES - RP - C005.2)	Ionic Burden (mg/ cm ²)							Non-Volatile Residue (DI Water Extraction) (mg/ cm ²)	Silicon Oil Presence by FTIR (Hexane Extraction) ABSENT
	Anions			Cations					
Count per cm ²	Cl ⁻	NO ₃ ²⁻	SO ₄ ²⁻	Ca ²⁺	Mg ²⁺	K ⁺	Na ²⁺		
< 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/ cm ²)							Non-Volatile Residue (DI Water Extraction) (mg/ cm ²)	Silicon Oil Presence by FTIR (Hexane Extraction) ABSENT
	Anions			Cations					
Count per cm ²	Cl ⁻	NO ₃ ²⁻	SO ₄ ²⁻	Ca ²⁺	Mg ²⁺	K ⁺	Na ²⁺		
< 1,200	< 0.75	< 0.4	< 0.1	< 0.4	< 0.01	< 0.05	< 0.04	< 10	

Contact Us

For sales enquiries: enquiries@brightway919.com
 Tel: +(603) 3343 1007, 3343 1094 Fax: +(603) 3341 4800

www.brightway919.com

QUALITY ACHIEVEMENTS

Brightway®

ISO 9001 : 2008 (Brightway, Laglove, Biopro)

for the following activities
Manufacture of Natural (Latex) and Synthetic Latex (Nitrile) Examination,
Surgical and Industrial Gloves & Nitrile Sheath

ISO 13485 : 2003, EN ISO 13485 :2012 (Brightway, Laglove, Biopro)

for the following activities
Manufacture of Natural (Latex) and Synthetic Latex (Nitrile) Examination,
Surgical and Industrial Gloves & Nitrile Sheath

ISO 13485 : 2003 (Brightway)

for the following activities
Manufacture of Natural (Latex) and Synthetic Latex (Nitrile) Examination and Surgical Gloves

Directive 89/686/EEC Article 11B (Brightway)

for the following activities
Manufacture of Chemical Protective Latex & Nitrile Gloves

Directive 89/686/EEC Article 11B (Laglove)

for the following activities
Manufacture of Chemical Protective Latex & Nitrile Gloves

Directive 89/686/EEC Article 11B (Biopro)

for the following activities
Manufacture of Chemical Protective Latex & Nitrile Gloves

Directive 93/42/EEC on medical devices, Annex V (Brightway)

for the following products
Natural (Latex) and Synthetic Latex (Nitrile) Surgical Gloves

Directive 93/42/EEC on medical devices, Annex V (Laglove)

for the following products
Natural (Latex) and Synthetic Latex (Nitrile) Surgical Gloves

Directive 93/42/EEC on medical devices, Annex V (Biopro)

for the following products
Natural (Latex) and Synthetic Latex (Nitrile) Surgical Gloves

CMDCAS Canadian Medical Devices Conformity Assessment System

FOOD & DRUG ADMINISTRATION REGISTERED 510 K

(See overleaf for details of Approvals)

1. Brightway Holdings Sdn Bhd
21 Pre market approvals
2. Laglove (M) Sdn Bhd
22 Pre market approvals
3. Biopro (M) Sdn Bhd
5 Pre market approvals

KOSHA – South Korea

TGA – Australia

CGSB - Canada

EC Type Examination Certificate

EEC Directive 89/686/EEC Article 10
as last amended by EEC Directive 96/58/EEC
Personal Protective Equipment



Contact Us

For sales enquiries: enquiries@brightway919.com

Tel: +(603) 3343 1007, 3343 1094 Fax: +(603) 3341 4800

www.brightway919.com

510K Premarket Approval Summary



1.0) Brightway Holdings Sdn. Bhd

Registration No.: 9617444
Owner Operator No.: 9036471
510 K No.

1.1) Latex Exam Gloves

1.1.1)	Brightway Brand Latex Examination Gloves (Powdered) - Low protein claim	510 K No : k 990540
1.1.2)	Brightway Brand Latex Examination Gloves (Powder free)- Low protein claim	510 K No : k 990539
1.1.3)	Brightway Brand Colored Latex Examination Gloves (Powdered - Blue Color)- Low protein claim	510 K No : k 991752
1.1.4)	Brightway Brand Colored Latex Examination Gloves (Powder free - Blue Color)- Low protein claim	510 K No : k 991750
1.1.5)	Brightway Brand Polymer Coated Latex Examination Gloves (Powder Free)- Low protein claim	510 K No : k 990543
1.1.6)	Brightway Brand Chemotherapy Latex Examination Gloves (Powder free, Blue color & Non - Sterile)	510 K No : k 011728
1.1.7)	Brightway Brand Chemotherapy Latex Examination Gloves (Powder free, Blue color & Sterile)	510 K No : k 010856
1.1.8)	Latex Examination Gloves (Powdered, Sterile)	510 K No : k 032938
1.1.9)	Latex Examination Gloves (Powder free, Sterile)	510 K No : k 032940
1.1.10)	Brightway Brand Latex Examination Gloves (Powder Free, Chlorinated, Black colour)	510 K No : k 060658

1.2) Nitrile Exam Gloves

1.2.1)	Brightway Brand Nitrile Examination Gloves (Powdered)	510 K No : k 990542
1.2.2)	Brightway Brand Nitrile Examination Gloves (Powder free)	510 K No : k 990541
1.2.3)	Brightway Brand Colored Nitrile Examination Gloves (Powdered - Blue Color)	510 K No : k 990876
1.2.4)	Brightway Brand Colored Nitrile Examination Gloves (Powder free - Blue Color)	510 K No : k 990878
1.2.5)	Brightway Brand Colored Nitrile Examination Gloves (Powder Free - Orange Color)	510 K No : k 022878
1.2.6)	Brightway Brand Nitrile Examination Gloves (Powder Free, Chlorinated, Black Colour)	510 K No : k 060402
1.2.7)	Brightway Brand Nitrile Examination Gloves (Powder Free,Chlorinated,Grey Colour)	510 K No : k 102880

1.3) Surgical Gloves

1.3.1)	Brightway Brand Latex Surgical Gloves - Sterile (Powdered)	510 K No : k 992020
1.3.2)	Brightway Brand Latex Surgical Gloves - Sterile (Powder free)	510 K No : k 992021
1.3.3)	Brightway Brand Nitrile Surgical Gloves - Sterile (Powdered)	510 K No : k 991940
1.3.4)	Brightway Brand Nitrile Surgical Gloves - Sterile (Powder free)	510 K No : k 991939

2.0) Laglove (M) Sdn. Bhd.

Registration No.: 8043785
Owner Operator No.: 9003781
510 K No.

2.1) Latex Exam Gloves

2.1.1)	Latex Examination Gloves	510 K No : k 912988
2.1.2)	Laglove Brand Latex Examination Gloves (Powdered)- Low protein claim	510 K No : k 990285
2.1.3)	Laglove Brand Latex Examination Gloves (Powder free)- Low protein claim	510 K No : k 990270
2.1.4)	Laglove Brand Colored Latex Examination Gloves (Powdered - Blue Color)- Low protein claim	510 K No : k 991748
2.1.5)	Laglove Brand Colored Latex Examination Gloves (Powder free - Blue Color)- Low protein claim	510 K No : k 991749
2.1.6)	Laglove Brand Polymer Coated Latex Examination Gloves (Powder Free)- Low protein claim	510 K No : k 990268
2.1.7)	Laglove Brand Latex Examination Gloves (Powdered), Non-Sterile - (Pink, Green, Violet)	510 K No : k 092499
2.1.8)	Laglove Brand Latex Examination Gloves (Powder Free), Non-Sterile - (Pink, Green, Violet)	510 K No : k 093193

2.2) Nitrile Exam Gloves

2.2.1)	Laglove Brand Nitrile Examination Gloves (Powdered)	510 K No : k 990415
2.2.2)	Laglove Brand Nitrile Examination Gloves (Powder free)	510 K No : k 990420
2.2.3)	Laglove Brand Colored Powdered Nitrile Examination Gloves (Blue)	510 K No : k 990883
2.2.4)	Laglove Brand Colored Powder Free Nitrile Examination Gloves (Blue)	510 K No : k 990882
2.2.5)	Laglove Brand Colored Powdered Nitrile Examination Gloves (Green / Purple)	510 K No : k 010861
2.2.6)	Laglove Brand Colored Powder Free Nitrile Examination Gloves (Green / Purple)	510 K No : k 010860
2.2.7)	Laglove Brand Nitrile / Neoprene Powder Free Examination Gloves	510 K No : k 010863
2.2.8)	Laglove Brand Double Polymer Coated Nitrile Examination Gloves (Powder Free - Blue Colour)	510 K No : k 042618
2.2.9)	Laglove Brand Colored Nitrile Examination Gloves (Powdered), Non-Sterile (Pink Colour)	510 K No : k 092498
2.2.10)	Laglove Brand Colored Nitrile Examination Gloves (Powder Free), Non-Sterile (Pink Colour)	510 K No : k 093335

2.3) Surgical Gloves

2.3.1)	Laglove Brand Latex Surgical Gloves - Sterile (Powdered)- Low protein claim	510 K No : k 992018
2.3.2)	Laglove Brand Latex Surgical Gloves - Sterile (Powder free)- Low protein claim	510 K No : k 992019
2.3.3)	Laglove Brand Nitrile Surgical Gloves - Sterile (Powdered)	510 K No : k 991949
2.3.4)	Laglove Brand Nitrile Surgical Gloves - Sterile (Powder free)	510 K No : k 991950

3.0) Biopro (M) Sdn. Bhd.

Registration No.: 9710315
Owner Operator No.: 9028328
510K No.

3.1) Latex Exam Gloves

3.1.1)	Biopro Brand Latex Examination Gloves (Powder free - Low protein claim)	510 K No : k 960467
3.1.2)	Correct Touch Powder Free 911 Latex Examination Gloves (Powder free - Blue)	510 K No : k 992358

3.2) Nitrile Exam Gloves

3.2.1)	Nitrilon TM Correct - Touch Nitrile Examination Gloves (Powdered)	510 K No : k 981304
3.2.2)	Nitrilon TM Correct - Touch Nitrile Examination Gloves (Powder free)	510 K No : k 981333

3.3) Surgical Gloves

MDL No : Applied by CT International

3.3.1)	Sterile Surgical Natural Latex Gloves	510 K No : k 891622
--------	---------------------------------------	---------------------