Brightway®

SERVICE
EXCELLENCE
INNOVATION
QUALITY


- 240mm (9½")
- 300mm (12")
- 330mm (13")
- 355mm (14")
- 400mm (16")
- 480mm (19")
- 530mm (21")
- 600mm (24")

MANUFACTURER AND GLOBAL DISTRIBUTOR OF VARIOUS TYPES AND LENGTHS OF 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 42 lines and is capable of producing 250 million gloves per month. With a total workforce of 2500 people, Product Innovation & Process Improvements are our key to salisty 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 al 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 starled operating in 1988. It houses 17 production lines, inclusive of 7 state-of-the-art double former lines with an output of 133 million pieces per month. Located at Kawasan Perindustrian Sultan Hishamuddin, Port Klang, Selangor : it is also equipped to 'slip sheet', pack and load containers.

## 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.

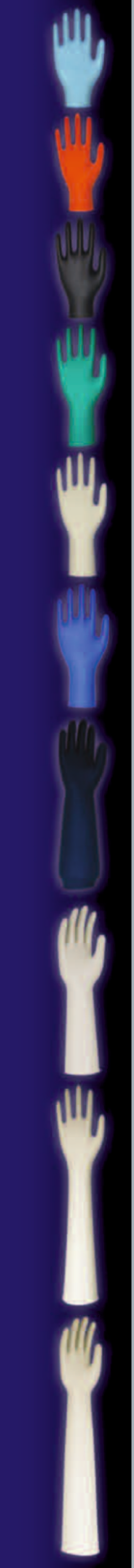
## BRIGHTWAY CLEANROOM

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-DIWater System which is able to produce consistent high purityDI 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 (p) particle counter. Anions & Cat-ions are tested with the Ion Chromatograph machine and Zinc Content, using a Spectrophotometer.





# 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
- 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 & 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 & 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) | Silicon Oil Presence by FTIR (Hexane Extraction) |
| | Anions | | | Cations | | | | | |
| Count per $cm^2$ | $Cl^-$ | $NO_3^{2-}$ | $SO_4^{2-}$ | $Ca^{2+}$ | $Mg^{2+}$ | $K^+$ | $Na^{2+}$ | (mg/ $cm^2$) | ABSENT |
| < 700 | < 0.25 | < 0.15 | < 0.02 | < 0.1 | < 0.005 | < 0.03 | < 0.02 | < 6 | |

| 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) | Silicon Oil Presence by FTIR (Hexane Extraction) |
| | Anions | | | Cations | | | | | |
| Count per $cm^2$ | $Cl^-$ | $NO_3^{2-}$ | $SO_4^{2-}$ | $Ca^{2+}$ | $Mg^{2+}$ | $K^+$ | $Na^{2+}$ | (mg/ $cm^2$) | ABSENT |
| < 1,200 | < 0.15 | < 0.20 | < 0.05 | < 0.2 | < 0.05 | < 0.05 | < 0.05 | < 10 | |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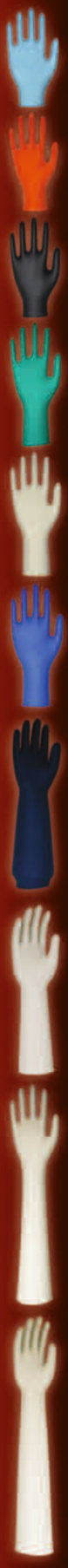
# LATEX GLOVES



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 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 & 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 & 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) | Silicon Oil Presence by FTIR (Hexane Extraction) |
| | Anions | | | Cations | | | | | |
| Count per $cm^2$ | $Cl^-$ | $NO_3^{2-}$ | $SO_4^{2-}$ | $Ca^{2+}$ | $Mg^{2+}$ | $K^+$ | $Na^{2+}$ | (mg/ $cm^2$) | 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/ $cm^2$) | | | | | | | Non-Volatile Residue (DI Water Extraction) | Silicon Oil Presence by FTIR (Hexane Extraction) |
| | Anions | | | Cations | | | | | |
| Count per $cm^2$ | $Cl^-$ | $NO_3^{2-}$ | $SO_4^{2-}$ | $Ca^{2+}$ | $Mg^{2+}$ | $K^+$ | $Na^{2+}$ | (mg/ $cm^2$) | ABSENT |
| < 1,200 | < 0.75 | < 0.4 | < 0.1 | < 0.4 | < 0.01 | < 0.05 | < 0.04 | < 10 | |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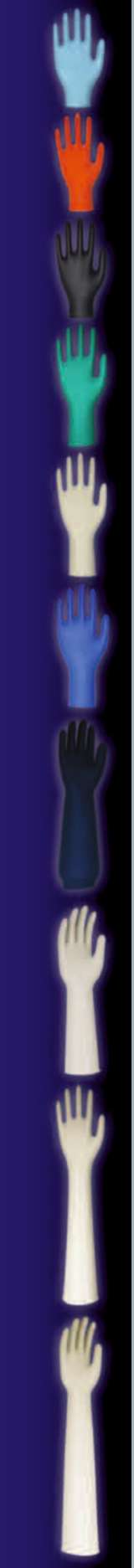
# CLEAN ROOM GLOVES



Whether latex or synthetic, sterile or non-sterile, hand-specific or ambidextrous, Brightway Gloves offers a portfolio of gloves that will meet a wide variety of needs. Brightway Pharmaceutical Gloves are clean-processed and designed to meet the demands of pharmaceutical, medical device producers, biotech and contract manufacturers in controlled environments, as well as professionals

**Design & Features :**

- Sterile Nitrile
- Sterile Latex
- Non Sterile Latex
- Sterile Polyisoprene
- Sterile Neoprene

**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.

**Available as per ISO / Class Standards :**

- ISO 4/ Class 10 or higher
- ISO 5/ Class 100 or higher
- ISO 6/ Class 1000 or higher
- ISO 7/ Class 10000 or higher

**Sterilization :**

Gamma Irradiation or EO Sterilized

**Applications :**

Clean Room

**Cleanroom Nitrile Gloves and Latex 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) | Silicon Oil Presence by FTIR (Hexane Extraction) |
| | Anions | | | Cations | | | | | |
| Count per $cm^2$ | $Cl^-$ | $NO_3^{2-}$ | $SO_4^{2-}$ | $Ca^{2+}$ | $Mg^{2+}$ | $K^+$ | $Na^{2+}$ | (mg/ $cm^2$) | ABSENT |
| < 700 | < 0.25 | < 0.15 | < 0.02 | < 0.1 | < 0.005 | < 0.03 | < 0.02 | < 6 | |

| 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) | Silicon Oil Presence by FTIR (Hexane Extraction) |
| | Anions | | | Cations | | | | | |
| Count per $cm^2$ | $Cl^-$ | $NO_3^{2-}$ | $SO_4^{2-}$ | $Ca^{2+}$ | $Mg^{2+}$ | $K^+$ | $Na^{2+}$ | (mg/ $cm^2$) | ABSENT |
| < 1,200 | < 0.15 | < 0.20 | < 0.05 | < 0.2 | < 0.05 | < 0.05 | < 0.05 | < 10 | |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## QUALITY STANDARDS AND REGISTRATION

ISO 9001 : 2000,
ISO 13485 : 2003:
EN ISO 13485 : 2012
Canadian Medical Devices Conformity Assessment System (CMDCAS)
TGA Mark -Australia
NF Mark - France
CGSB - Canada
Korea Occupational Safety & Health Agency - Korea

**CE DIRECTIVES**
93/42/EEC-Annex V (Surgical Gloves) 89/686/EEC-Article 11B (Chemical Protective Latex Gloves - Chemo/ Acid Gloves)
**89/686/EECArticle 10**
**CMDCAS**
Canadian Medical Devices Conformity Assessment System
**US FDA's Quality System Regulation (QSR)**
FDA 510K Premarket Approvals - 48 Approvals
Certificate of Foreign Medical Device Manufacturer - Japan

CE 0120 EUROPE
CE EUROPE
ISO 9001 SGS
ISO 13485 SGS
UKAS MANAGEMENT SYSTEMS 005
CGSB CANADA
TGA AUSTRALIA
NF FRANCE
FDA REGISTERED U.S.A
KOSHA

# QUALITY ACHIEVEMENTS

**ISO 9001 : 2008**
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**
for the following activities
Manufacture of Natural (Latex) and Synthetic Latex (Nitrile) Examination, Surgical and Industrial Gloves & Nitrile Sheath

**ISO 13485 : 2003**
for the following activities
Manufacture of Natural (Latex) and Synthetic Latex (Nitrile) Examination and Surgical Gloves

**Directive 89/686/EEC Article 11B**
for the following activities
Manufacture of Chemical Protective Latex & Nitrile Gloves

**Directive 89/686/EEC Article 11B**
for the following activities
Manufacture of Chemical Protective Latex & Nitrile Gloves

**Directive 89/686/EEC Article 11B**
for the following activities
Manufacture of Chemical Protective Latex & Nitrile Gloves

**Directive 93/42/EEC on medical devices, Annex V**
for the following products
Natural (Latex) and Synthetic Latex (Nitrile) Surgical Gloves

**Directive 93/42/EEC on medical devices, Annex V**
for the following products
Natural (Latex) and Synthetic Latex (Nitrile) Surgical Gloves

**Directive 93/42/EEC on medical devices, Annex V**
for the following products
Natural (Latex) and Synthetic Latex (Nitrile) Surgical Gloves

**CMDCAS Canadian Medical Devices Conformity Assessment System**

**EC Type Examination Certificate**
EEC Directive 89/686/EEC Article 10
as last amended by EEC Directive 96/58/EEC
Personal Protective Equipment

CE 0120 EUROPE · CE EUROPE · SYSTEM CERTIFICATION ISO 9001 SGS · SYSTEM CERTIFICATION ISO 13485 SGS · UKAS MANAGEMENT SYSTEMS · CGSB CANADA · TGA AUSTRALIA · NF FRANCE · FDA REGISTERED U.S.A · KOSHA


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(169521-T)
**(Manufactured at)**
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42100 Klang, Selangor Darul Ehsan, Malaysia.
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