



"Enhancing Life Through Protection"

BIOFLEXX™

BIODEGRADABLE FENTANYL/CHEMO TESTED NITRILE GLOVES

Nitrile Powder-free gloves suitable for moderate to high-risk work environments.



This biodegradable non-sterile glove features an advanced formulation providing you with the ultimate fit, comfort, and protection. With its high strength and excellent protective features, this glove is ideal for nearly all clinical settings and work environments, including working with cytotoxic chemicals such as opioid fentanyl citrate and different chemotherapy drugs.

KEY FEATURES AND BENEFITS

- Biodegrading efficacy of 90% after just 490 days*
- Tested against opioid fentanyl citrate and chemo drugs, offerings extreme protection when needed most.
- High quality formulation for exceptional fit and comfort providing better tactile sensitivity when needed most.
- Available in colors violet blue and black.
- Available in 100 count and 200 count boxes.

RECOMMENDED AREAS OF USE

- Border Patrol & Customs
- Law Enforcement Routine Duties
- Pre-Hospital Patient Care
- Health Care
- Crime Laboratories
- Fire Fighters
- Clean Up Workers
- Special Operations and Decontamination

STANDARDS/COMPLIANCE





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PRODUCT SPECIFICATIONS

| | |
|----------------------------|---|
| Product code | DUKESBIOFLEXXX2458089-00159 |
| Product type | Biodegradable Powder-Free Examination Gloves, Non-sterile, Tested for use with Chemotherapy Drugs and Opioid Fentanyl Citrate |
| Product Conformance | This product meets current version of ASTM D6319, ASTM D6978, ASTM D5526, ASTM D5511 and is manufactured in accordance with a quality management that conforms to ISO 9001 and ISO 13485 |
| Material | Nitrile Butadiene Rubber |
| Cuff Finishing | Beaded |
| Color | Violet Blue/Black |
| Surface Finishing | Fingers textured |

| No. | Test Method | Purpose of Testing | Result Summary |
|-----|-------------------|---|---|
| 1 | ASTM D5526 | To determine the degree and rate of anaerobic biodegradation of materials in accelerated landfill conditions. This is a long term test that replicates the landfill environment of low heat, high pressure, limited oxygen, no light and low moisture. | 30% biodegradation in 202 days.* |
| 2 | ASTM D5511 | To determine the degree and rate of anaerobic biodegradation of materials in high-solids anaerobic-digestion conditions, which replicates the anaerobic digester or landfill bioreactor environment. | 90% biodegradation in 490 days.* <i>(Above results are based on a real-time study.)</i> |

| Features | | | | |
|--|-------------|--------------------|-------------|--------------------|
| Powder free, fingertip textured, ambidextrous, standard cuff, violet blue colour | | | | |
| Physical Dimensions | | | | |
| Length (mm) | ≥ 230 | Median ≥ 240 | ≥ 230 | Median ≥ 240 |
| Palm (centre of palm) (mm) | ≥ 0.05 | Median ≥ 0.05 | 0.07 ± 0.02 | Median 0.07 ± 0.02 |
| Finger (13mm ± 3mm from tip) | 0.08 ± 0.03 | Median 0.08 ± 0.03 | 0.10 ± 0.02 | Median 0.10 ± 0.02 |
| Physical Properties | | | | |
| Tensile strength (MPa) | | | | |
| Before ageing | ≥ 18 | N/A | ≥ 18 | N/A |
| After ageing | ≥ 16 | N/A | ≥ 16 | N/A |
| Elongation (%) | | | | |
| Before ageing | ≥ 500 | N/A | ≥ 500 | N/A |
| After ageing | ≥ 400 | N/A | ≥ 400 | N/A |
| Median Force at Break (N) | | | | |
| Before ageing | N/A | ≥ 6 | N/A | ≥ 6 |
| After ageing | N/A | ≥ 6 | N/A | ≥ 6 |



BIOFLEXX

BIODEGRADABLE FENTANYL/CHEMO TESTED NITRILE GLOVES

BUILD A SUSTAINABLE FUTURE WITH DUKES BIOFLEXX BIODEGRADABLE GLOVES.

END-OF-LIFE SOLUTION FOR NITRILE GLOVES

Creating sustainability is entrenched firmly at the core of DUKES™. It is an integral part of the way we do business. Holding to our vision to be recognised as a caring company to the community and environment, DUKES™ constantly innovates with a passion to bring a positive change to all that we do.

DUKES™ Biodegradable glove, BIOFLEXX™, is one of DUKES™ latest green initiatives in helping to create a better environment. It is our contribution to provide an end-of-life solution to nitrile gloves.

HOW IT WORKS

DUKES's BIOFLEXX™ is a polymerised "food source", specially formulated to attract microbes found especially in landfills. This biodegradation method is strictly enzymatic.

When bacteria consume the BIOFLEXX™ material, they excrete an enzyme that dissolves and de-polymerises the polymer chain, allowing the microbes to break down the remaining polymer naturally.

TECHNOLOGY EXPLAINED

DUKES™ BIOFLEXX™ drop-in technology integrates the existing manufacturing process without compromising product quality. It comprises of an organic additive used to accelerate the biodegradation rate of gloves in biologically active landfills and anaerobic digesters.





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WHY CHOOSE DUKES™ BIOFLEXX™ GLOVES?

1. Validated Biodegradation Rate

DUKES™ BIOFLEXX™ biodegrading efficacy has been verified by an independent lab, Eden Research Laboratory, using ASTM D5526 and ASTM D5511 methods. [Table 1]

| No. | Test Method | Purpose of Testing | Result Summary |
|-----|-------------------|---|--|
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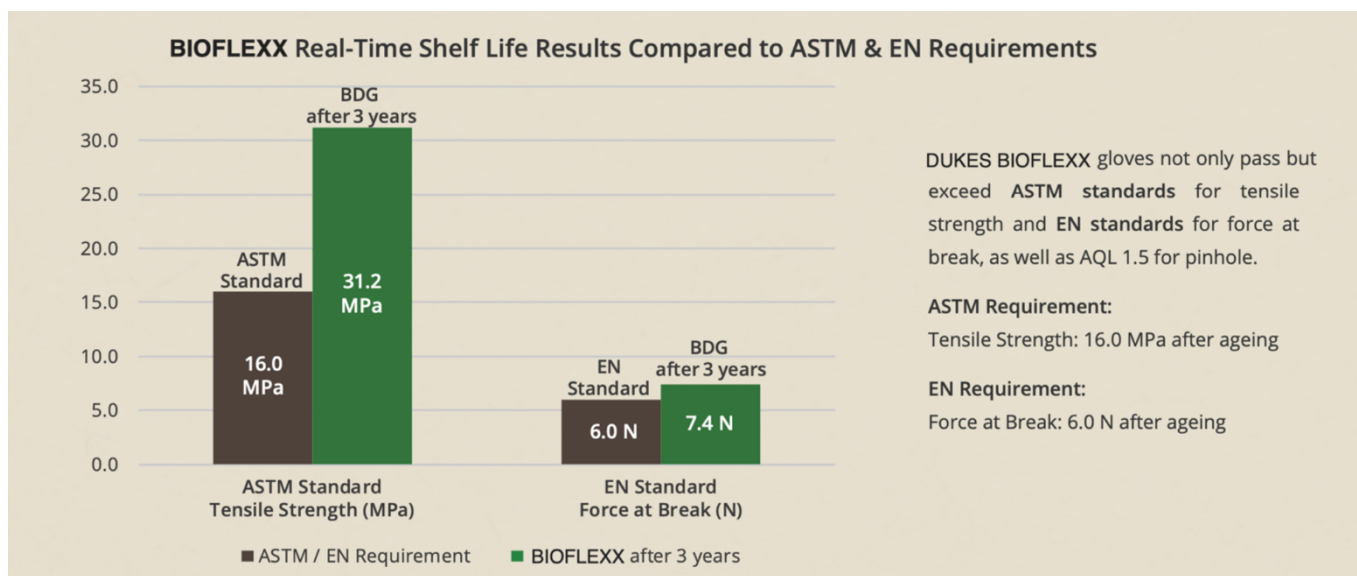
Table 1: Biodegradation test results based on ASTM D5526 & ASTM D5511.

*The actual biodegradation rates will vary depending on the landfill conditions and the biological activity of microorganisms surrounding the nitrile gloves.

2. Retain Glove Properties

Gloves with BIOFLEXX™ technology do not biodegrade prior to disposal. The unique formulation only allows the biodegradation process to begin when surrounded by microbes present in a landfill environment. Real-time shelf life study results prove that the physical property of DUKES™ BIOFLEXX™ gloves remains unchanged up to 3 years. [Chart 1]

Chart 1: BIOFLEXX real-time shelf life results.





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3. Tested Safe For Biocompatibility & Food Contact

DUKES™ BIOFLEXX™ gloves have been proven safe for use against skin according to ISO standards, as well as with food handling according to U.S. FDA, Japan Food Sanitation, European regulation (EU) No 10/2011, (EC) 1935/2004 and BfR XXI German Recommendation. [Table 2]

| | ISO 10993-5 | ISO 10993-10 | ISO 10993-10 | Food Contact | Food Contact | Food Contact |
|----------------|------------------------------|-------------------------|----------------------------|-----------------|----------------------|----------------------------------|
| Test | Cytotoxicity Test | Primary Skin Irritation | Dermal Sensitisation Study | 21 CFR 177.2600 | Japan Sanitation Law | EN 1186, EN 13130 & CEN/TS 14234 |
| Result Summary | Non-cytotoxic at 10% extract | Non-irritating | Non-sensitising | Pass | Pass | Pass |
| Compliance | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

Table 2: List of biocompatibility and food contact test results for BIOFLEXX.

DUKES™ BIOFLEXX™ GLOVE SPECIFICATIONS

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| Median Force at Break (N) | | | | |
| Before ageing | N/A | ≥ 6 | N/A | ≥ 6 |
| After ageing | N/A | ≥ 6 | N/A | ≥ 6 |

THE BENEFITS OF DUKES™ BIOFLEXX™ BIODEGRADABLE GLOVES

- FDA (510k) approval since August 2018
- Liable solution for proper glove disposal
- Proven to biodegrade based on ASTM D5526 (simulating landfill condition)
- Better ASTM D5511 biodegradation performance compared to other industry players
- Maintains the same glove properties and shelf life as standard nitrile gloves, proven by real-time shelf life test results
- Enhances your company’s environmental and green efforts
- Supports sustainability for a greener environment
- DUKES™ quality and consistency is proven

Declaration letter

We, Dukes International (Australia) Co Pty Ltd / Dukes Manufacturing (Thailand/Malaysia) Co.,Ltd hereby declare that we do not use latex, vinyl or PVC in any form as a raw material for the production of “Nitrile powder free gloves” under “teX”, “teX PLUS”, “BIOFLEXX”, “SURGIXAL”, “OATSOFT”, “SILX”, “CANNAGRIP”, “GripeXX”, “CHEMIXX”, “KontaX”, “liteserV” and “GripfiX” brands.

The products manufactured and supplied by Dukes International Co Ltd and are free from latex, vinyl or PVC.

We declare that the above-mentioned productst are in conformity with the provisions of U.S FDA 510(k) Class LZA, LZC, OPJ and EU MDR 2017/745. Technical file no: OT-TF-001 and all supporting documentations are retained under premises of the manufacturer.

Sincerely,



Mark Verhoeven
Co-founder/Chief Executive Officer
Dukes International Co Pty Ltd (Australia)
Dukes International Co.,Ltd (Thailand)
Dukes International LLC (USA)

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