

Nitrile Exam Gloves

2020 v12.18

PRODUCT DESCRIPTION / SPEC SHEET

| MATERIAL FIELD | DATA INFORMATION NEEDED | | | | | | | | | | | | |
|--|--|-------------------|---------------------------|--|--------------|---|--------------|---|--------------|---|--------------|--|--------------|
| SUPC / ITEM NUMBER: | N/A | | | | | | | | | | | | |
| ITEM DESCRIPTION: | <p>KEY FEATURES: Nitrile examination gloves, powder-free, straight fingers, textured surface, beaded cuff, ambidextrous, violet blue colour</p> <p>REGULATORY COMPLIANCE:</p> <ul style="list-style-type: none"> ● US FDA Quality System Regulation (QSR) ● US FDA 510(k) Registered, CE Certified ● CE Medical Device Directive 93/42/EEC Class I ● EN 455-1 :2000, EN 455-2:2015, EN 455-3:2015 ● ASTM 06319, ASTM 06124 and ASTM 05712 | | | | | | | | | | | | |
| BRAND: | KENteam | | | | | | | | | | | | |
| <p>GTIN / UPC: (14 digit no.) (1 CASE)</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="text-align: center; padding: 5px;">SIZING VARIATIONS</th> <th style="text-align: center; padding: 5px;">UPC for 1 CASE (10 boxes)</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">KENteam Disposable Nitrile Examination Gloves (XS)</td> <td style="text-align: center; padding: 5px;">850017735439</td> </tr> <tr> <td style="padding: 5px;">KENteam Disposable Nitrile Examination Gloves (S)</td> <td style="text-align: center; padding: 5px;">850017735446</td> </tr> <tr> <td style="padding: 5px;">KENteam Disposable Nitrile Examination Gloves (M)</td> <td style="text-align: center; padding: 5px;">850017735453</td> </tr> <tr> <td style="padding: 5px;">KENteam Disposable Nitrile Examination Gloves (L)</td> <td style="text-align: center; padding: 5px;">850017735460</td> </tr> <tr> <td style="padding: 5px;">KENteam Disposable Nitrile Examination Gloves (XL)</td> <td style="text-align: center; padding: 5px;">850017735477</td> </tr> </tbody> </table> | | SIZING VARIATIONS | UPC for 1 CASE (10 boxes) | KENteam Disposable Nitrile Examination Gloves (XS) | 850017735439 | KENteam Disposable Nitrile Examination Gloves (S) | 850017735446 | KENteam Disposable Nitrile Examination Gloves (M) | 850017735453 | KENteam Disposable Nitrile Examination Gloves (L) | 850017735460 | KENteam Disposable Nitrile Examination Gloves (XL) | 850017735477 |
| SIZING VARIATIONS | UPC for 1 CASE (10 boxes) | | | | | | | | | | | | |
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| KENteam Disposable Nitrile Examination Gloves (S) | 850017735446 | | | | | | | | | | | | |
| KENteam Disposable Nitrile Examination Gloves (M) | 850017735453 | | | | | | | | | | | | |
| KENteam Disposable Nitrile Examination Gloves (L) | 850017735460 | | | | | | | | | | | | |
| KENteam Disposable Nitrile Examination Gloves (XL) | 850017735477 | | | | | | | | | | | | |

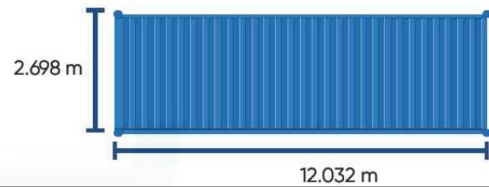
BIOBX

PACKING:

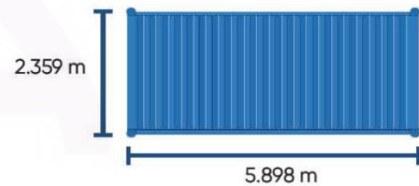
| SIZING VARIATIONS | QUANTITY / DIMS |
|-------------------|-----------------------------|
| PER BOX | 100 PIECES |
| PER CASE | 10 BOXES |
| CASE DIMENSIONS | 36.4 cm x 24.8 cm x 24.5 cm |

1 X 40' HC - CONTAINER PACKING SPECS

- **[PALLETIZED ONLY]** 40ft HC: 2,100 CTN w/ pallet, 46.4449 CBM, 20 pallets (105 ctn / pallet)
- **[PALLETIZED & STUFFING]** 40ft HC: 2,700 CTN w/ pallet and stuffing, 59.7149 CBM, 25 pallets (108 ctn / pallet)
- **[NON PALLETIZED & FLOOR-LOADED]** 40ft HC: 3,200 CTN w/o pallet, full stuffing, 70.7732 CBM (floor-loaded)

CONTAINER 40 FT STANDARD HIGH CUBE:**1 X 20' - CONTAINER PACKING SPECS**

- **[PALLETIZED ONLY]** 20ft: 1,000 CTN w/ Pallet, no stuffing, 22.2936 CBM, 10 pallets (100 ctn / pallet)
- **[PALLETIZED & STUFFING]** 20ft: 1,200 CTN w/ Pallet and stuffing, 26.54 CBM, 12 pallets (100 ctn / pallet)
- **[NON PALLETIZED & FLOOR-LOADED]** 20ft: 1,500 CTN w/o Pallet, full stuffing (floor-loaded), 33.1750CBM

CONTAINER 20 FT STANDARD:**SIZES:**

XS, S, M, L, XL

GROSS WEIGHT: (PER CASE)
(total weight of item + tare weight)

| SIZING VARIATIONS | WEIGHTS PER CASE |
|--|------------------|
| KENteam Disposable Nitrile Examination Gloves (XS) | 4 kg |
| KENteam Disposable Nitrile Examination Gloves (S) | 4.15 kg |
| KENteam Disposable Nitrile Examination Gloves (M) | 4.35 kg |
| KENteam Disposable Nitrile Examination Gloves (L) | 4.75 kg |
| KENteam Disposable Nitrile Examination Gloves (XL) | 5.25 kg |

NET WEIGHT: (PER CASE)
(total weight of item)

| SIZING VARIATIONS | WEIGHTS PER CASE |
|--|------------------|
| KENteam Disposable Nitrile Examination Gloves (XS) | 3.8 kg |
| KENteam Disposable Nitrile Examination Gloves (S) | 4.0 kg |
| KENteam Disposable Nitrile Examination Gloves (M) | 4.15 kg |
| KENteam Disposable Nitrile Examination Gloves (L) | 4.5 kg |
| KENteam Disposable Nitrile Examination Gloves (XL) | 5 kg |

| | |
|------------------------------------|-----------------|
| LENGTH: (PER CASE) | 14" |
| WIDTH: (PER CASE) | 10" |
| HEIGHT: (PER CASE) | 10" |
| CUBE: (PER CASE) | 14" x 10" x 10" |
| MANUFACTURER / TRUE VENDOR: | KENTEAM |

MANUFACTURER PRODUCT CODE (MPC):

Lot # Identification on Finished Goods

| | |
|-----------------------|--|
| Lot Number Structure: | = YMMPPPPSS (9 digits) |
| Y: | = Year of Packing |
| MM: | = Month of Packing |
| PPPP: | = KENTEAM's Packing Work Order # (PWO) |

| | |
|------------------------------------|--|
| CATCH WEIGHT: (YES / NO) | |
|------------------------------------|--|

VENDOR STORAGE CODE: (1 CASE)

| SIZING VARIATIONS | SKUs for 1 CASE |
|--|-------------------------|
| KENteam Disposable Nitrile Examination Gloves (XS) | bbx-kt-nitrile-xs-1case |
| KENteam Disposable Nitrile Examination Gloves (S) | bbx-kt-nitrile-s-1case |
| KENteam Disposable Nitrile Examination Gloves (M) | bbx-kt-nitrile-m-1case |
| KENteam Disposable Nitrile Examination Gloves (L) | bbx-kt-nitrile-l-1case |
| KENteam Disposable Nitrile Examination Gloves (XL) | bbx-kt-nitrile-xl-1case |

| | |
|--|---|
| VENDOR STORAGE TEMPERATURE (MIN): | Store in a cool, dry place, and avoid excessive heat, store temperature should be between 5-30°C. |
| VENDOR STORAGE TEMPERATURE (MAX): | 31°C+ |
| VENDOR TI: | 20 |

| | |
|---|-------------------------------|
| VENDOR HI: | 5 |
| VENDOR TOTAL SHELF LIFE: | 3 years |
| GUARANTEED SHELF LIFE WHEN RECEIVED AT SYSCO (COOLER ITEMS): | 5 years from Manufacture Date |
| IS PRINTED CASE EXPIRATOR or PACK DATE: | Manufactured Date |
| SOURCE SHIP-FROM: | Malaysia |
| BSCC BILLED: (YES / NO) | N/A |
| FOB COST PER CS / LB: | |
| DELIVERED COST PER CS / LB: | |
| FREIGHT COST PER CS / LB: | |
| PICKUP ALLOWANCE PER CS / LB: | |
| THIRD LINE DESCRIPTION / ATTRIBUTES: | |

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A GLOVE FOR EVERY MARKET FULFILL EVERY NEED

KENTTEAM is one of the world's leading manufacturers of Surgical, Examination, High Risk and Multipurpose gloves with worldwide coverage in every key market sector. Our Malaysia-based factories meet and exceed the most stringent international quality and product standards, giving us the ability to serve virtually any country around the world.

Clients all over the world are satisfied with our gloves' quality. From the broad-based and volume-driven Medical markets to the niche Industrial and Specialty markets, KENTTEAM supply single-use Nitrile gloves for a variety of end-markets and applications.

With the help of our 4,200 employees, we are heading toward 5 Billion US Dollar of revenue this year and now we are capable to supply 720 million boxes of nitrile gloves per year to fulfill our clients' need. Stay safe and healthy with KENTTEAM now.

VISION

To be one of the world's best organizations in providing solutions for hand-protection for world wide markets.

MISSION

World leader in manufacturing & distribution of all range of gloves. We will continue to grow organically, focusing on providing our products with consistent quality at competitive costs, supported by superior customer care to generate above industry returns to our shareholders."



KENteam

Nitrile Exam Gloves Powder Free, Standard Cuff



Kenteam Glove is like putting on a second skin. Its absolute tactility commends it to delicate procedures and jobs plus an assured tensile strength and resistance to substances expected of a nitrile glove. You owe it to yourself to try this exceptional nitrile glove from Kenteam.



| KENTEAM GLOVE | | |
|-----------------------------|------------------|--------------|
| Length (mm) | ≥ 240 | |
| Thickness Measurements (mm) | | |
| Palm (centre of Palm) | Min. 0.06 | |
| Finger | Min. 0.09 | |
| Physical Properties | Before Ageing | After Ageing |
| Tensile Strength (MPa) | ≥ 14 | ≥ 14 |
| Elongation (%) | ≥ 500 | ≥ 400 |
| Inspection Levels & AQL | Inspection Level | AQL |
| Watertightness | G1 | 1.5 |
| Physical Dimensions | S2 | 4.0 |
| Physical Properties | S2 | 4.0 |
| Visual Inspection (Major) | S4 | 2.5 |
| Visual Inspection (Minor) | S4 | 4.0 |
| Particulate Residue | N = 5 | ≤ 2mg/glove |

FEATURES

- Fingertip textured
- Powder free
- Not made with natural rubber latex
- Textured surface
- Beaded cuff
- Ambidextrous
- Violet blue colour

PACKAGING

100 gloves by weight per box
10 boxes per carton

REGULATORY COMPLIANCE

FDA, FDA 510(k), CE Marking MDD Class I

STANDARDS

EN455 part 1, 2, 3, ASTM D6319,
ASTM D6124, ASTM D5712

Kenteam Nitrile Glove is a nitrile powder free disposable glove which is made from acrylonitrile butadiene rubber. It is specially designed for applications in industries, such as janitorial use, medical industries, product examination, gardening tasks and cleaning.

Kenteam Nitrile Glove is designed to minimize tackiness to provide better grip and comfort. It is also specially formulated to offer protection against mild chemicals, oil and fats.



Made in Malaysia



KENteam

**NITRILE POWDER FREE
EXAMINATION GLOVES**

KENteam

DISPOSABLE NITRILE EXAMINATION GLOVE

OPEN HERE



DISPOSABLE POWDER FREE AMBIDEXTROUS NON-STERILE 100 PCS

Distributed by :
Packaging by :
Manufactured by :

XS
S
M
L
XL

KENteam

**NITRILE POWDER FREE
EXAMINATION GLOVES**

KENteam



Made in Malaysia

KENteam

Kenteam Glove is like putting on a second skin. Its absolute tactility commends it to delicate procedures and jobs plus an assured tensile strength and resistance to chemical expected of a nitrile glove. You owe it to yourself to try this exceptional nitrile glove from Kenteam.

This glove is for single use only and should be replaced if damaged.

Gloves are to be stored in a cool, dry place. Avoid direct sunlight.



Made in Malaysia

KENteam Nitrile Exam Outer Case Photos







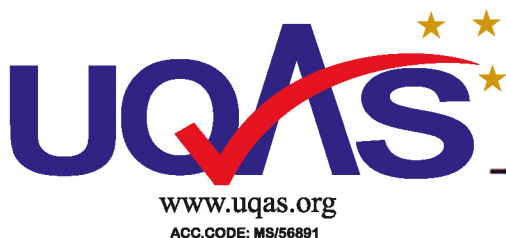
Certificate of Registration



| | |
|--------------------------------|---|
| Reference No | : IAS/MYS/10264 |
| Applicant Name | : KENTTEAM SDN BHD No.6-2, PJS 8/12A Dataran Mentari Petaling Jaya Selangor-46150, Malaysia. |
| Type of Product | : NITRILE EXAMINATION GLOVES |
| Model | : NITRILE GLOVE |
| Directives | : Medical Devices Directive 93/42/EEC |
| Test Standards | : EN 455-1:2000 EN 455-2:2015 EN 455-3:2015 |
| Initial Issue Date | : 10 th Sep' 2020* |
| Certificate Issue Date | : 10 th Sep' 2020 |
| Certificate Expiry Date | : 09 th Sep' 2021* |



The above product is found in compliance with Medical Devices Directive 93/42/EEC and test report based on EN 455-1:2000, EN 455-2:2015, EN 455-3:2015. Certificate is valid for three years (10th Sep' 2020– 09th Sep' 2023) from the date of initial registration. Upon successful completion of yearly audit a new certificate with an extended validity will be issued. Further clarification regarding the scope of this certification may be obtained by consulting the organization.





Certifying Authority

KENTteam

INTEGRATED ASSESSMENT SERVICES PVT.LTD.

Web : www.iasiso.com, E-Mail: info@iasiso.com, Ph: +91-44-42693624 / 26162670

Establishment Registration & Device Listing

FDA Home Medical Devices Databases



1 result found for **Owner Operator Name :**

kenteam

New Search

| Establishment Name | Registration Number | Current Registration Yr |
|--|---------------------|-------------------------|
| KENTEAM SDN BHD MALAYSIA | No number listed | 2021 |
| <ul style="list-style-type: none"> Polymer Patient Examination Glove - DERMAGRIP POWDER FREE BLACK NITRILE PATIENT EXAMINATION GLOVES, NON-STERILE | | Manufacturer |
| <ul style="list-style-type: none"> Latex Patient Examination Glove | | Manufacturer |
| <ul style="list-style-type: none"> Latex Patient Examination Glove - DERMAGRIP-X POWDER FREE LATEX EXAMINATION GLOVES WITH SKIN-CARE INGREDIENTS (VITAMIN A, VITAMIN B, OC-LIPOIC ACID, EUCAL | | Manufacturer |
| <ul style="list-style-type: none"> Polymer Patient Examination Glove - DERMAGRIP POWDER FREE BLUE NITRILE PATIENT EXAMINATION GLOVES, NON-STERILE, TESTED FOR USE WITH CHEMOTHERAPY DRUGS | | Manufacturer |
| <ul style="list-style-type: none"> Patient Examination Glove, Specialty - DERMAGRIP POWDER FREE BLUE NITRILE PATIENT EXAMINATION GLOVES, NON-STERILE, TESTED FOR USE WITH CHEMOTHERAPY DRUGS | | Manufacturer |
| <ul style="list-style-type: none"> Polymer Patient Examination Glove | | Manufacturer |
| <ul style="list-style-type: none"> Polymer Patient Examination Glove - DERMAGRIP-P POWDER FREE PINK NITRILE EXAMINATION GLOVES, NON-STERILE | | Manufacturer |
| <ul style="list-style-type: none"> Polymer Patient Examination Glove - Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile, Tested For Use With Chemotherapy Drugs | | Manufacturer |
| <ul style="list-style-type: none"> Patient Examination Glove, Specialty - Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile, Tested For Use With Chemotherapy Drugs | | Manufacturer |
| <ul style="list-style-type: none"> Polymer Patient Examination Glove - DERMAGRIP-N/MULTIPLE/WRP ASIA PACIFIC SDN BHD POWDER FREE NITRILE EXAMINATION GLOVES, NON-STERILE | | Manufacturer |
| <ul style="list-style-type: none"> Polymer Patient Examination Glove - GRAB GLOVES | | Manufacturer |

Establishment Registration & Device Listing

FDA Home Medical Devices Databases



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Establishment:
 KENTEAM SDN BHD
 C-13-3, Level 13, KL Trillion No. 338, Jalan Tun Razak
 Kuala Lumpur Wilayah Persekutuan Kuala L, MY 50400
Status: Active: Awaiting Assignment Of Registration Number
Date Of Registration Status: 2021

Owner/Operator:
 KENTEAM SDN BHD
 C-13-3, Level 13, KL Trillion No. 338, J
 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur MY 50400
Owner/Operator Number: 10078535

Official Correspondent:
 Chan Ching Jeat
 C-13-3, Level 13, KL Trillion No. 338, J
 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur MY 50400
Phone: 60-03-356135722

US Agent:
 Scott Chuang
 GIBMO International LLC
 145 Corte Madera Town Center, #188
 Corte Madera, CA US 94925
Phone: 415 6239888 Ext
Email: Schuang@Gibmo.Net

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Establishment Registration & Device Listing

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| New Search | Back To Search Results |
|--------------------------------|-----------------------------------|
| Proprietary Name: | GRAB GLOVES |
| Classification Name: | POLYMER PATIENT EXAMINATION GLOVE |
| Product Code: | LZA |
| Device Class: | 1 |
| Regulation Number: | 880.6250 |
| Medical Specialty: | General Hospital |
| Registered Establishment Name: | KENTTEAM SDN BHD |
| Premarket Submission Number: | K132354 |
| Owner/Operator: | KENTTEAM SDN BHD |
| Owner/Operator Number: | 10078535 |
| Establishment Operations: | Manufacturer |

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|------------------------------|---|
| Device Classification Name | Polymer Patient Examination Glove |
| 510(K) Number | K132354 |
| Device Name | POWDER FREE BLUDE NITRILE PATIENT EXAMINATION GLOVE, NON-STERILE |
| Applicant | ADVANCED HEALTH PRODUCTS, LOT 60 & 61 LORONG SENAWAND 3/2 SENAWANG INDUSTRIAL ESTATE Seremban, Negeri Sembilan Darul, MY 70450 |
| Applicant Contact | Francis V |
| Correspondent | ADVANCED HEALTH PRODUCTS, LOT 60 & 61 LORONG SENAWAND 3/2 SENAWANG INDUSTRIAL ESTATE Seremban, Negeri Sembilan Darul, MY 70450 |
| Correspondent Contact | Francis V |
| Regulation Number | 880.6250 |
| Classification Product Code | LZA |
| Date Received | 07/29/2013 |
| Decision Date | 06/30/2014 |
| Decision | Substantially Equivalent (SESE) |
| Regulation Medical Specialty | General Hospital |
| 510k Review Panel | General Hospital |
| Summary | Summary |
| Type | Traditional |
| Reviewed By Third Party | No |
| Combination Product | No |

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