

TECHNICAL DATA SHEET



Description

50600M: Purple Nitrile XTRA - XS
50601M: Purple Nitrile XTRA - S
50602M: Purple Nitrile XTRA - M
50603M: Purple Nitrile XTRA - L
50604M: Purple Nitrile XTRA - XL

Non-powdered, textured finger tips, ambidextrous, extended cuff, single use. Color: Purple.

Dimensions

| | Palm width | Length (target) |
|------------------|------------|-----------------|
| Extra Small (XS) | 70 mm | 310 mm |
| Small (S) | 80 mm | 310 mm |
| Medium (M) | 95 mm | 310 mm |
| Large (L) | 110 mm | 310 mm |
| Extra Large (XL) | 120 mm | 310 mm |

Properties (target)

Median force at break before aging: 11.0 N
Median force at break after aging: 9.0 N
Residual powder: 1.0 mg/glove
Thickness middle finger: 0.15 mm
Thickness palm: 0.12 mm
Thickness cuff: 0.11 mm

Indication

To protect patient and user from cross-contamination. These gloves are also approved for use during chemotherapy activities.

Counter indication

Not intended for applications involving direct exposure to harsh chemicals, where heavy duty industrial gloves are required.

Main materials

Base material: Nitrile Butadiene.
Accelerators: ZDBC (Zinc Dibutyldithiocarbamate) and ZDEC (Zinc Diethyldithiocarbamate).

Not intentionally formulated or treated with any of the following: Bisphenol A, colophony (rosin), natural rubber latex, brominated flame retardants, phthalates (DBP, BBP, DEHP, DMEP, DNOP, DPP, DIPP, DIDP, DINP).



Sterilization

Products are non-sterile.

Packaging

Shipping case of 500 units.
50 units are placed within 1 dispenser and 10 dispensers are placed within a shipping case.
Bar coding: GS1-128 symbology, linear, on shipping case and dispenser box.

Manufacturing

Products are manufactured in Thailand.
The quality system of the manufacturing sites is ISO 13485 compliant.

Regulatory information

Product CE marked as per 93/42/EEC Directive on Medical Devices.
Class of the device: I.
Comply to EN 455-1, EN 455-2, EN 455-3, EN 455-4, EN 374-2 (Level 2) and EN 374-3.

Storage

Store in a dry and cool place, away from intense sources of heat and sources of radiation.
Keep as much as practicably possible in its shipper box.

Shelf life

5 years, from the date of manufacture.