

TECHNICAL DATA SHEET

Description

Reference: 52003M L

Non-powdered, textured finger tips, ambidextrous, single use.

Color:

Purple.

Dimensions:

Palm width Length

Extra Small (XS) 70 mm > 240 mm

Small (S) 80 mm > 240 mm

Medium (M) 95 mm > 240 mm

Large (L) 110 mm > 240 mm

Extra Large (XL) 120 mm > 240 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: 0.09 mm



Indication

To protect patient and user from cross-contamination

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/or 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)

Sterilisation

Products are non-sterile.

Shelf Life

5 years, from the date of manufacture

Packaging

References 52000M, 52001M, 52002M, 52003M:

Shipping case of 1000 units.

10 dispenser boxes of 100 units in each shipping case.

Reference 52004M:

Shipping case of 900 units.

10 dispenser boxes of 90 units in each shipping case.

Bar coding: GS1-128 symbology, linear, on shipping case and dispenser box.

Manufacturing

Products are manufactured in Thailand/Malaysia.

The quality system of the manufacturing sites is ISO 13485 compliant

Regulatory Information

Product CE marked as per Regulation (EU) 2017/745 on Medical Devices. Class of the device: I.

Product CE marked as per (EU) 2016/425 regulation on Personal Protective Equipment. Class of the equipment: PPE Category III Comply with EN 455-1, -2, -3, -4; EN 21420 ; EN 374-1 Type B (J K T), -2, -3; EN 374-2, EN 374-4, EN 16523-1, EN ISO 374-5, ISO 16604. AQL of 1.0 for freedom from holes according to EN 455-1.

Storage

Store in a dry and cool place, away from intense sources of heat and

sources of radiation.

This document was created using the most recent information. In the interest of continuous improvement, the characteristics of the product may change without prior notice.