

## TECHNICAL DATA SHEET

### Description

Reference: 52001M S

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.*