

TECHNICAL DATA SHEET

Description

Reference: 13941 M

Non-powdered, textured finger tips, ambidextrous, optimized packaging, single use. Color: grey

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: 8.0 N

Median force at break after aging: 8.0 N

Residual powder: 1.0 mg/glove

Thickness middle finger: 0.09 mm

Thickness palm: 0.08 mm

Thickness cuff: 0.06 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: ZMBT (Zinc 2-mercaptobenzothizole), ZDEC (Zinc Diethyldithiocarbamate), DPG (diphenylguanidine).

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 13938, 13939, 13940, 13941 and 13942:

Shipping case of 2000 units.

10 dispenser boxes of 200 units in each shipping case.

Reference 13943:

Shipping case of 1700 units.

10 dispenser boxes of 170 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 manufacturing site's quality system conforms to ISO13485.

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

Complies with EN455-1, EN455-2, EN455-3, EN455-4; EN 420; EN ISO 374-1, EN374 -2, EN374-4, EN16523-1, EN ISO 374-5.

AQL of 1.0 for freedom from holes according to EN 455-1.

Approved for Food Contact as per Regulation 1935/2004 and 10/2011.

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.

Improvement, the characteristics of the product may change without prior notice.