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Technical Data Sheet

Sensicare® PI Micro

Sterile Synthetic Isolex Polyisoprene Powder-Free Surgical Gloves with Synthetic Polymer Coating

Reference & Size

MSG9655	MSG9660	MSG9665	MSG9670	MSG9675	MSG9680	MSG9685	MSG9690
5,5	6,0	6,5	7,0	7,5	8,0	8,5	9,0

Primary Material

Powder-Free Synthetic Isolex Polyisoprene with Synthetic Polymer Coating
Powder Free in accordance with EN455-3 and ISO 21171

Donning Agent

Synthetic Polymer Coating E-Z glide as an inner Multiple layer donning technology with Polyacrylic and surfactant (Inner surface coated for dry and damp hand donning)

Color

Cream

Grip

Smooth

Former (Mold) Design

Anatomical with straight fingers and independent thumb to replicate hand shape improving comfort and reducing hand fatigue.

Cuff Design

Tapered, beaded cuff design with special texture to adhere to the surgical gown to prevent roll down.

Chemical Additives (Accelerators)

Zinc Diethyldithiocarbamate (ZDEC), Zinc Mercaptobenzothiazole (ZMBT)
Residual chemical levels below detectable level according to UPB/P/003a test method

Leachable Protein (per EN455-3 using ASTM D5712 (Modified Lowry Protein Method)

No natural rubber latex proteins and allergens.

Thickness (per ASTM D3577 ≥ 0,10 mm)

Finger Tip	0,20 mm
Palm	0,18 mm
Cuff	0,15 mm

CE 2797 2 LATEX STERILE R

Retention period: End of life and support period

TDS_*SurgicalGlove*_MSG96xx-EN03

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Sensicare® PI Micro

Sterile Synthetic Isolex Polyisoprene Powder-Free Surgical Gloves with Synthetic Polymer Coating

Length (mm) & Width (mm) Per EN455-2

MSG9655	MSG9660	MSG9665	MSG9670	MSG9675	MSG9680	MSG9685	MSG9690
293	298	300	300	299	300	299	300
73	80	85	90	100	105	110	115

Force @ Break Before Challenge Testing (per EN455-2 ≥ 9 N)

13,1 N

Force @ Break After Challenge Testing (per EN455-2 ≥ 9 N, 7 days 70°C in an oven)

12 N

Freedom from Holes (per EN 455 AQL 1.5)

0,65 AQL Before Packaging

0,65 AQL Final Inspection 0,65 AQL Final Inspection

Viral Penetration

Tested and passed, in accordance with ISO16604 / ASTM F 1671

Chemical Resistance

The resistance to chemicals has been assessed in accordance with EN 16523-1 and chemo drugs under ASTM D 6978.

Results and recommendations for use with chemicals and chemo drugs can be obtained on request

Sterilization

Gamma Radiation, Sterility Assurance Level 10^{-6}

Expiration Date

35 Months from Date of Manufacture
Manufacture and Expiration Dates are printed on packaging (YYYY-MM format)

Packaging

Polyethylene peel pouch
Packaged in space-saving folded configuration
50 pairs per dispenser box / 4 boxes per carton / 200 pairs per carton

Regulations and Quality Standards

Medline manufacturing locations are certified to EN ISO 13485 by BSI
Product meets requirements of the EU Medical Device Directive (93/42/EEC)
Product meets requirements of European harmonized standards EN 455-1, -2, -3 and -4

PPE Certification

Under the requirements of Personal Protective Equipment Regulation (EU)2016/425 Category III. Complies with standards EN 420, EN ISO 374-1, EN 374-2, EN 16523-1, EN 374-4, EN ISO 374-5 and ISO 16604.

Storage Recommendations

Protect from freezing, avoid excessive heat. Shield from direct sunlight, fluorescent lighting, x-rays, moisture and ozone.

Manufacturer's Address

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093 USA.

European Office

Medline International BV
Nieuwe Stationstraat 10
6811 KS Arnhem -
The Netherlands

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