

# STERILE LATEX GLOVES

Security  
and maximal  
protection



# > General presentation

## Description

The sterile gloves are ambidextrous (examination) or anatomical (intervention and surgery), powder-free, and are made of natural rubber latex and chemical additives. They have a micro-textured surface and are cream (examination and intervention) or natural (surgery) in colour. The beaded cuff comes in a length of 240 mm (examination) or 290 mm (intervention and surgery). They are presented in a sterile state for uses requiring perfect aseptic conditions.

## Classification

Non-reusable, sterile gloves are intended for medical use for cross-contamination protection of the patient and user. They are to be considered "invasive medical devices for temporary or short-term use" within the meaning of the European directive concerned, and as such are Class I Sterile (for examination and intervention gloves) or Class IIa (for surgery gloves).

### Examindex Stérile® powder-free

Latex examination glove,  
sterile (gamma rays), single use,  
powder-free, ambidextrous,  
standard cuff minimum 240 mm

#### Product codes

6/7 S: 448003  
7/8 M: 448004  
8/9 L: 448005

#### Packaging

Box of 50 pairs,  
Carton of 4 boxes

### Interventex® powder-free

Latex intervention glove,  
sterile (gamma rays), single use,  
powder-free, anatomical shape,  
extra-long cuff minimum 290 mm

#### Product codes

6: 452006  
6,5: 452065  
7: 452007  
7,5: 452075  
8: 452008  
8,5: 452085

#### Packaging

Box of 50 pairs,  
Carton of 4 boxes

### Surgitex® powder-free

Latex surgery glove,  
sterile (gamma rays), single use,  
powder-free, anatomical shape,  
extra-long cuff minimum 290 mm

#### Product codes

6: 446106  
6,5: 446165  
7: 446107  
7,5: 446175  
8: 446108  
8,5: 446185

#### Packaging

Box of 50 pairs,  
Carton of 4 boxes

#### Colour codes for the different glove types



= Examination



= Intervention



= Surgery

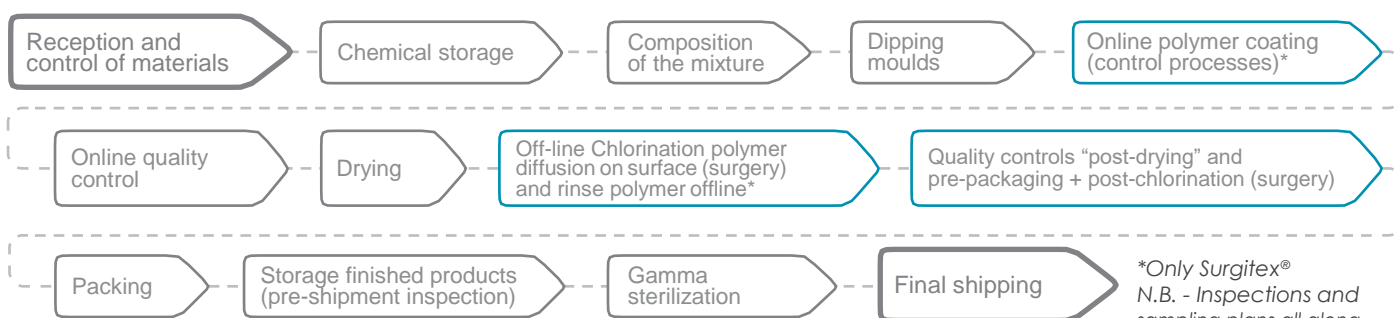
## Composition (materials and chemical agents)

### Formulation of **Examindex Stérile®**, **Interventex®**, **Surgitex®** gloves

60% HA Latex (Natural Rubber Latex), Stabilizer, Freesil (Antifoam), ZDBC (Zinc Dibutyldithiocarbamate Accelerator), ZDEC (Zinc Diethyldithiocarbamate Accelerator), ZnO (Zinc Oxide), TiO<sub>2</sub> (Titanium Dioxide), Sulphur (Sulphur), Anti-Oxidant (Anti-Oxidant), Dispersing agent, Polyacrylic polymer, Biocide (Anti-bacteria).

N.B. – Do not contain Thiuram, Methanethiol (Mercaptain) & Benzothiazole. Do not contain Phthalates, or animal derivatives.

## Manufacturing process (summary)



\*Only Surgitex®  
N.B. - Inspections and sampling plans all along these steps according to Quality System process.

## Technical specifications

Criteria	Standards	Results Examindex Stérile®, Interventex®, Surgitex®
DETECTION OF PINHOLES (tests and level control)	EN 455-1	AQL 1.5 for examination and intervention AQL 1.0 for surgery (Acceptance Quality Limit)
DIMENSIONS length	EN 455-2	240 mm minimum for examination 290 mm minimum for intervention and surgery
width		Examination: S 85 / M 95 / L 106 (±5mm) Intervention: S.677 / S.6,5 83 / S.7 89 / S.7,5 95 (±5mm) S.8 102 / S.8,5 108 (+ 6mm) Surgery: S.677 / S.6,5 83 / S.7 89 / S.7,5 95 (±5mm) S.8 102 / S.8,5 108 ± 6mm)
FORCE AT BREAK before aging	EN 455-2	≥ 6 N (for examination) ≥ 9 N (for intervention and surgery)
after aging (70 ±2°C pendant 7 jours)		≥ 6 N (for examination) ≥ 9 N (for intervention and surgery)
EXTRACTABLE PROTEIN (according to Lowry method)	EN 455-3	< 50 µg/g
ENDOTOXINES	EN 455-3	< 20 EU/pair of gloves
SHELF LIFE	EN 455-4	3 years (recommended)
THICKNESS (SIMPLE) cuff paume finger	ASTM D3577	≥ 0.10mm (examination) / 0.14mm (Intervention) / 0.17mm (Surgery) ≥ 0.12mm (examination) / 0.16mm (Intervention) / 0.20 0.02mm (Surgery) ≥ 0.14mm (examination) / 0.23 0.02mm (Intervention) / ±0.23 0.02mm (Surgery)
ULTIMATE ELONGATION before aging after aging (70 ±2°C during 7 days)	ASTM D3578	≥ 650% (examination) and ≥ 750% (intervention and surgery) ≥ 500% (examination) and ≥ 560% (intervention and surgery)
RESIDUAL POWDER	EN 455-3	≤ 2 mg/glove
GLOVES AVERAGE WEIGHT	NO STANDARD	6,8 g (examination size M) 9.9 g (intervention size 7,5) 11 g (surgery size 7,5)
MANUFACTURING PLACE		Malaysia

N.B. - Testing reports and quality certificates on request.



# PACKAGING AND MARKING

## > Pallet

- Complete Europe Pallet of 60 cartons or 12.000 pairs
- Possible mix of size and/or material by multiple of 12 cartons per layer
- Dimensions ground 0,80 x 1,20 m
- Average weight 300 kg examination, 435 kg intervention and 435 kg surgical
- Neat loading, filmed labelled and circled with guarantee strip
- Returnable Europe Pallet



## > Carton

- Carton of 4 boxes of 50 pairs or 200 pairs  
31,5 L x 29 H x 28 l approximately  
(26,5 H examination)
- Identification of sizes and materials by colour codes, letters and numbers
- Traceability by batch number and expiry date
- Average weight 5 kg examination, 7,3 kg intervention, and 7,3 kg surgery
- Recyclable material
- Possible customization on request

## > Box

- Box of 50 pairs packed peel-pack
- Identifying types of gloves by colour codes, letters and numbers.
- Traceability by batch number and expiry date
- Average weight 1,25 kg examination, 1,82 kg intervention, and 1,82 kg surgery
- Symbols according to regulatory standards
- Possible customization on request

Batch number  
(day, month, year  
of production)

Expiry date (maximum  
recommended date)

Contain latex



Waste recycling



Do not reuse  
Single use



Do not use  
if package  
is damaged



CE marking



Peelable pouch

