

## Embra<sup>®</sup> Examination Gloves, Latex FLEX, Powder-Free

REF: 821000, 821001, 821002, 821003, 821004

Disposable Examination Gloves, Latex, Powder-Free.

### Key Features

- ▶ Elastic examination glove made of natural latex material with low latex protein content.
- ▶ Powder-free, ambidextrous with rolled rim and textured fingertips.
- ▶ Strong glove with a good fit and comfort.
- ▶ Excellent grip.
- ▶ Inner coated for easy donning.
- ▶ Latex raw material from FSC certified plantation.








### Recommendations for use



Basic cleaning



Basic procedures  
and wards

REF	DESCRIPTION	SIZE CODE	Overall Length	Pack Count dispenser/carton
821000	Examination Gloves, Latex FLEX, Powder-Free, XS, Off white		240 mm	100 / 1000
821001	Examination Gloves, Latex FLEX, Powder-Free, S, Off white		240 mm	100 / 1000
821002	Examination Gloves, Latex FLEX, Powder-Free, M, Off white		240 mm	100 / 1000
821003	Examination Gloves, Latex FLEX, Powder-Free, L, Off white		240 mm	100 / 1000
821004	Examination Gloves, Latex FLEX, Powder-Free, XL, Off white		240 mm	90 / 900

Sales Unit: Transport Carton

## Regulations

The product complies with legal requirements for medical devices.



<b>REACH regulation:</b>	The products covered by this data sheet do not contain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), including any of the Substances of Very High Concern (SVHC) as listed in the latest available version of the Candidate List published by European Chemicals Agency (ECHA).
<b>Freedom of holes:</b>	AQL 1.5
<b>Force at break (N):</b>	≥ 6.0 N (before and after challenge test)
<b>Biological evaluation:</b>	Total quantity of powder residues for powder-free glove: < 2 mg/glove Cytotoxicity tested acc. to EN ISO 10993-5 Irritation and skin sensitization tested acc. to EN ISO 10993-10
<b>Leachable proteins:</b>	In accordance with EN 455-3 using Modified Lowry Protein Assay
<b>Compliance with legal requirements:</b>	Medical Device Regulation (EU) 2017/745, MDR Class I
<b>Compliance with product standards:</b>	EN 455: 1 – 4
<b>Chemical Resistance:</b>	Tested in accordance with EN 16523-1
<b>Food safety:</b>	Approved for food industry. Not recommended to use with acidic foods (incl. ≥ 3% Acetic acid).
<b>Other tests performed:</b>	Viral penetration according to EN ISO 374-5 Chemical residue
<b>Quality standards:</b>	EN ISO 13485
<b>Label information and packaging compliance:</b>	EN ISO 15223-1, EN ISO 20417

## Material

Product Part	Raw Material & Characteristics
<b>Palm</b>	Natural rubber latex, single wall thickness min. 0.08 mm
<b>Finger</b>	Natural rubber latex, single wall thickness min. 0.08 mm

## Warnings & Recommendations

### Warnings

The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur.

The product contains natural latex which may cause allergic reactions including anaphylactic shock. The product contains dithiocarbamates – not to be used in case of hypersensitivity to these substances.

### Storage Recommendation

Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone.

### Disposal Recommendation

Dispose in accordance with local regulations.

### Shelf Life

3 years

## Packing Information

Package	Material	Size ( L x W x H ) mm
Single Pack	N/A	N/A
Dispenser Pack	Cardboard, ECF quality	240 x 122 x 65
Transport Carton	ECF quality, Corrugated board	340 x 249 x 250
Packing Tape	PVC-free, Transparent	N/A

## Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
821000	N/A	06438129370508	06438129570502
821001	N/A	06438129370515	06438129570519
821002	N/A	06438129370522	06438129570526
821003	N/A	06438129370539	06438129570533
821004	N/A	06438129370546	06438129570540

Embra's mission is to develop responsible healthcare solutions focused on lowering the environmental impact while heightening quality for patients and caregivers. Together we can make a positive difference, so thank you for choosing Embra.