






Product Specification



Product Codes	LO01
Product type	Examination and protective
UDI DI Code	Printed on the box and carton
Chlorinated or Not	Chlorinated
Color	Milky White
Medical grade : (EU) 2017/745	Class I
Protection type: (EU) 2016/425	Category III
Food Contact:	Pass done by SGS
Stretchiness	≥6N
Material	Natural rubber
Palm thickness:	min. 0.08mm
Finger thickness:	min. 0.08mm
Sterility	Non-Sterile
Texture	Texture at the fingertips
Internal surface	Powder-Free, Max. 2.0mg/glove
Impermeability level (AQL)	≤1.5
Shape	ambidextrous
Cuff	Rolled
Glove length	≥240mm
Glove palm width	XS: 70mm, S: 80mm, M:95mm, L:110mm, XL: 120mm.
Suitable for sensitive skin	Yes.
Shelf Time:	3 years
storage temperature	5-35°C degrees

Product EAN-13 Codes	XS	S
	 8 859130 638216	 8 859130 638223
	M	L
	 8 859130 638230	 8 859130 638247
		XL
		 8 859130 638254

Package Specification

Boxes/Carton:	10
Carton G. Weight:	XS-5.0KG S-5.6KG, M-5.9KG, L-6.6 KG , XL-7 KG
Maximum boxes per EU Pallet:	800 boxes/ pallet
EU Pallets Qty per full truck:	33
EU Pallet G. Weight:	21.5kg
G. Weight per pallet for XS	421.5kg
G.Weight per pallet for S	469.5kg
G.Weight per pallet for M	493.5kg
G. Weight per pallet for L	549.5kg
G. Weight per pallet for XL	581.5kg



Box size: 240mm x 122mm x 65mm



GLOVE SPECIFICATION

SETINO

Product Specification Group Code:	LOOOGF-B-EU-M-NS	LO-01
Product Code:	DLOFBOG	
Product name:	LO-01 LATEX EXAMINATION AND PROTECTIVE GLOVE CREAM POWDERFREE , Non Sterile, Chlorinated	
Grade:	EU Spec, Medical Grade	

GENERAL INFORMATION:

Type:	Single Use
Marking:	Gloves are not marked to designated size.
Shape:	Ambidextrous
Material:	Natural Rubber Latex
Cuff:	Rolled off
Surface:	Textured at finger tip

Thickness: (single wall according to ASTM D3578, ASTM D3767)	Finger: Min. 0.08mm	Palm: Min. 0.08mm
Residual Powder: (according to EN 455-3, EN ISO 21171)	Max. 2mg/glove, PowderFree	Force at break: (according to EN 455-2)
Protein Content: (according to EN 455-3)	Max. 50ug/g	Before Aging: min. 6N After Aging: min 6N
Length: (according to EN 455-2)	Min. 240mm	Tensile Strength: (according to ASTM D3578, ASTM D412, ASTM D573)
Available Sizes & Palm Width (mm): (according to EN 455-2)	XS ≤ 80, S: 80+/-10, M:95+/-10, L:110+/-10, XL: ≥ 110	
AQL: 1.5		
Before Aging:		Min. 18Mpa
After Aging:		Min. 14Mpa
% Elongation: (according to ASTM D3578, ASTM D412, ASTM D573)		Before Aging: min. 650% After Aging: min. 500%

Storage: 3 years storage life (date of expiration see on the box). Keep area cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Copper-ions discolor the glove. Protect gloves against ultraviolet light sources, as sunlight and oxidizing agents. Storage above 30°C will lead to accelerated aging and should be avoided.

STANDARDS, GUIDELINES AND QUALITY CERTIFICATION

(Every mentioned standard is used in the latest edition.)

Certification :	ISO 9001, ISO 13485, ISO 45001, ISO 14001		
Conformity to guidelines :	Medical Device Regulation (EU)2017/745 :Class I under Rule1 and Rule 5 according to Annex VIII (Subject to EU Declaration of Conformity to brand owner) Personal Protective Equipment Regulation (EU) 2016/425 : Category I or Category III (Subject to EU Type-Examination Certificate)		
Conformity to standards :	<u>Medical</u>	<u>PPE</u>	<u>PPE</u>
	EN 455	CAT I	CAT III
	ASTM D3578	EN 420	EN 420
			EN 374
			EN 16523-1
Conformity to food regulation :	1935/2004		
Potential allergenic ingredients:	Dithiocarbamate type (for further information, the actual version of the ingredients list is given on request)		

Please report any incidents with the products to contact@setino.com without undue delay. Our Product Safety Officers will review all information provided and might contact the original informant for further clarification

