

PRODUCT SPECIFICATION

SecondSkin

Light

POWERED BY
SEMPERIT

Spec code: N-1135-24B
Product name: SecondSkin Light
Date of issue: 21.05.2019

GENERAL INFORMATION

Type: single-use disposable examination or protective glove
Marking: all information on dispenser box
Shape: ambidextrous - straight fingers
Material: Nitrile Butadiene Rubber (NBR)
Colour: lavender-blue
Inner: online chlorinated / powderfree
Outer: no treatment
Cuff/Surface: rolled cuff / finger textured

Thickness: (double measured)	Finger: min. 0.14 mm	Palm: min. 0.12 mm	Cuff: min. 0.10 mm
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Residual powder:	≤ 2 mg / glove
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Force at break (according to EN 455-2)	med. 6.0 N (during shelf life)
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Length:	median 240 mm
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Available Sizes:	S (6-7) M (7-8) L (8-9) XL (9-10)
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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 discolour the glove. Protect gloves against ultraviolet light sources, as sunlight and oxidizing agents. Storage above 30°C will lead the accelerated aging and should be avoided.

STANDARDS, GUIDELINES AND QUALITY CERTIFICATION

Quality certification: ISO 9001, ISO 13485
Conformity to guidelines: Personal Protective Equipment (EU) 2016/425: CE cat. III
Medical Device Directive 93/42/EEC: CE Class I

Conformity to standards:

EN 420
EN 455
ASTM D6319

EN ISO 374-1:2016/Type B	Level	EN 374-4:2013 Degra. %
Sodium Hydroxide 40%	6	-4.3
Formaldehyde 37%	6	28
Hydrogen Peroxide 30%	6	18

Conformity to food regulation:

1935/2004 

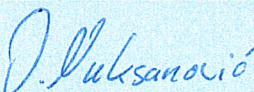


EN ISO 374-5:2016	Level
Protection against bacteria&fungi	pass
Protection against viruses	pass

WARNING AND REPORTING SYSTEM

Potentially allergic ingredients: Dihiocarbamate type, Zinc-mercaptobenzothiazol
(For further information, the actual version of the ingredients list is given on request.)

Medical Device Vigilance and Reporting System: According to the official reporting criteria of MDD, incidents caused by examination gloves or surgical gloves must be reported immediately to our medical device reporting officer. Tel. +43 2630 310 ext. -510; Fax: 549

Caution! This product contains accelerators which may cause allergic reactions!

Established (Product Manager):	Reviewed (Production Manager):	Approved (CEO):
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