

PRODUCT SPECIFICATION

SecondSkin

POWERED BY
SEMPERIT

Strong

Spec code: N-1147-24B
 Product name: SecondSkin Strong
 Date of issue: 28.06.2016

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: regular blue
 Inner: online chlorinated / powderfree
 Outer: no treatment
 Cuff/Surface: rolled cuff / finger textured

Thickness: (double measured)	Finger: min. 0.18 mm	Palm: min. 0.16 mm	Cuff: min. 0.10 mm
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Residual powder: ≤ 2 mg / glove	Force at break (according to EN 455-2)	med. 6.0 N (during shelf life)
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Length: median 240 mm

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.

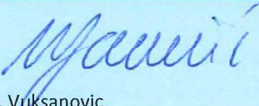
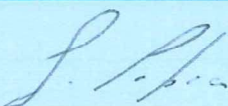
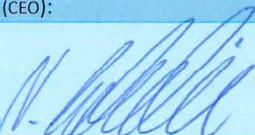
STANDARDS, GUIDELINES AND QUALITY CERTIFICATION

Quality certification: ISO 9001, ISO 13485
 Conformity to guidelines: Personal Protective Equipment 89/686/EEC: CE cat. III
 Medical Device Directive 93/42/EEC: CE Class I
 Conformity to standards: EN 420 EN 374-2: specified EN 374-3: Class 6
 EN 455 level 2 - AQL 1.5 Sodium Hydroxide 40%
 ASTM D6319 level 3: AQL <0.65 (G1)
 level 2: AQL <1.5 (G1)
 level 1: <4.0 (S4)
 Conformity to food regulation: 1935/2004 

WARNING AND REPORTING SYSTEM

Potentially allergic ingredients: Diisocarbamate type, Zinc-mercaptobenzothiazol
 (For further information, the actual version of the ingredients list is given on request.)
 Medical Device Villigance 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):  N. Vuksanovic	Reviewed (Sales Director):  G. Cappa	Approved (CEO):  N. Saladin
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