## PRODUCT SPECIFICATION



POWERED BY SEMPERIT

Spec code:

L-1159-24N

Product name:

SecondSkin Touch

Date of issue:

28.06.2016

**GENERAL INFORMATION** 

Type:

single-use disposable examination or protective glove

Marking: Shape:

all information on dispenser box ambidextrous - straight fingers

Material:

Natural Rubber Latex (NRL) natural white

Colour:

Inner:

polymer coated / powderfree

Outer: Cuff/Surface: no treatment

rolled cuff / fully textured

Thickness: (double measured)

Finger: min. 0.24 mm

Palm:

min. 0.20 mm

Cuff:

min. 0.14 mm

Residual powder:

≤2 mg/glove

Force at break (according to EN 455-2) med. 6.0 N

(during shelf life)

Length:

median 240 mm

**Available Sizes:** 

XS (5-6) S (6-7) M (7-8) L (8-9) XL (9-10)

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 Sodium

EN 455 **ASTM D3578**  level 2 - AQL 1.5 level 3: AQL < 0.65

level 1: <4.0

(G1) level 2: AQL <1.5 (G1)

(\$4)

Hydroxide 40%

527 1935/2004

WARNING AND REPORTING SYSTEM

Potentially allergic ingredients:

Conformity to food regulation:

Dihiocarbamate 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 offical 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 natural rubber latex which may cause allergic reactions, including anaphylacic responses!

Established (Product Manager):

Reviewed (Sales Director):

Approved (CEO):

N. Vuksanovic

G. Cappra

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