PRODUCT SPECIFICATION



POWERED BY SEMPERIT

Spec code:

N-1140-24S

Product name: Date of issue:

SecondSkin Style 28.06.2016

GENERAL INFORMATION

Type:

single-use disposable examination or protective glove

Marking: Shape: all information on dispenser box ambidextrous - straight fingers Nitrile Butadiene Rubber (NBR)

Material: Colour:

black

Inner:

online chlorinated / powderfree

Outer:

no treatment

Cuff/Surface:

rolled cuff / finger textured

Thickness:
(double measured)

Finger:

min. 0.18 mm

Palm:

min. 0.14 mm

Cuff:

min. 0.10 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:

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 Hydroxide 40%

EN 455 ASTM D6319 level 2 - AQL 1.5

level 3: AQL <0.65 (G1) level 2: AQL <1.5 (G1)

level 1: <4.0

(G1) (S4)

Conformity to food regulation:

1935/2004 577

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 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 accelerators which may cause allergic reactions!

Established (Product Manager):	Reviewed (Sales Director):	Approved (CEO):
Maluu'i N. Vuksanovic	G. Cappra 8-1-6-6	N. Saladin 1 - William
- 1/		

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