## PRODUCT SPECIFICATION



Spec code:

NOF-C0940

**Product name:** 

Semperguard® Style

Date of issue: **Article number:**  20/05/14

8167 6413.

. = 3 (size S), 5 (size M), 7 (size L), 9 (size XL)

## **GENERAL INFORMATION**

Type:

single-use disposable examination or protective glove

L (8-9)

Marking: Shape:

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

Material: Colour:

Inner:

online chlorinated/powder free

Outer:

no treatment

Cuff/Surface:

rolled cuff/fingertip textured

Thickness: (double measured)

Finger: min. 0.20 mm

Palm: min. 0.14 mm

Cuff: min. 0.10 mm

Residual powder: [according to EN 455-3]

≤ 2 mg / glove

Force at break:

med. 6.0 N (during shelf life)

Length:

median 240 mm

**Available Sizes:** 

S (6-7)

M(7-8)

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 to 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: AQL <4.0 (S4)

Conformity to food regulation: 1935/2004

## WARNING AND REPORTING SYSTEM

Potentially allergenic ingredients:

Dithiocarbamate 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 (PM/DM): Reviewed (QA/DM): Approved (HoM/DM): **Customer approval** Dr. R. Stempfer Mag. B. Schnetzlinger L. Millonig, MA

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Semperguard® Style NOF-C0940\_Version B\_May 2014 EN Replaces all previous versions