## PRODUCT SPECIFICATION



Spec code:

LCT-C0159

**Product name:** 

Semperguard® Latex IC powder free

Date of issue:

01/09/201429/08/14

Article number:

8137 8004.

. = 1 (size XS), 3 (size S), 5 (size M), 7 (size L), 9 (size XL)

## **GENERAL INFORMATION**

Type:

single-use disposable examination or protective glove

Marking: Shape:

all information on dispenser box ambidextrous - straight fingers Natural Rubber Latex (NRL)

Material: Colour:

natural white

Inner:

polymer coated/ powder free

Outer:

no treatment

Cuff/Surface:

rolled cuff/finger textured

Thickness: (double measured)

Finger: min. 0.22 mm

Palm: min. 0.22 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 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 5

EN 455 ASTM D3578

level 2 - AQL 1.5 level 3: AQL <0.65 (G1) level 2: AQL <1.5 (G1) level 1: AQL <4.0 (S4)

Sodium Hydroxide 40%

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 natural rubber latex which may cause allergic reactions, including anaphylactic responses!

Established (PM) Reviewed (QA): Approved (R&D) L. Millonig, MA R. Stempfer, MSc Dr. A. Weinert

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Semperguard® Latex IC powder free LCT-C0159\_Version D\_September 2014\_EN Replaces all previous versions