PRODUCT SPECIFICATION



Spec code:

LXF-C0150

Product name:

Semperguard® Latex powdered

Date of issue:
Article number:

01/09/2014 8139 8702.

. =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: Material: all information on dispenser box ambidextrous – straight fingers Natural Rubber Latex (NRL)

Colour: Inner: natural white lightly powdered

Outer: Cuff/Surface: no treatment

Thickness:

rolled cuff/fingertip textured

(double measured)

Finger: min. 0.20 mm

Palm: min. 0.16 mm

Cuff: min. 0.11 mm

Residual powder:

≤ 10 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:

5 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 3

EN 455

level 2 - AQL 1.5

Sodium Hydroxide 40%

ASTM D3578

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

Conformity to food regulation: 1935/2004

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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

DI Dr. R. Stempfer, MSc

Dr. A. Weinert

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Semperguard® Latex powdered LXF-C0150_Version B_September 2014_EN Replaces all previous versions