PRODUCT SPECIFICATION



Spec code:

NOT-C0367 290mm

Product name:

Semperguard® Nitrile Xtension

Date of issue: Article number: 13/10/14 8167 8086.

. = 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 Nitrile Butadiene Rubber (NBR)

Material: Colour:

blue

Inner:

online chlorinated/powder free

Outer:

no treatment

Cuff/Surface:

rolled cuff/fully textured

Thickness: (double measured)

Finger: min. 0.18 mm

Palm: min. 0.16 mm

Cuff: min. 0.10 mm

≤ 2 mg / glove

Force at break: [according to EN 455-2]

med. 6.0 N (during shelf life)

Length:

median 290 mm

Available Sizes:

Residual powder:

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 6 Sodium Hydroxide 40%

EN 455

level 2 - AQL 1.5 level 3: AQL <0.65 (G1) level 2: AQL <1.5 (G1) **ASTM D6319**

Conformity to food regulation: 1935/2004

level 1: AQL <4.0

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WARNING AND REPORTING SYSTEM

Potentially allergenic ingredients:

Dithiocarbamate type

(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): Reviewed (QA): Approved (R&D) Millonig, MA Dr. R. Schaller Dr. A. Weinert

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Semperguard® Nitrile Xtension NOT-C0367 290mm_Version B_October 2014_EN Replaces all previous versions