

PRODUCT SPECIFICATION

Spec code: NOF-035VB-N-3CZ (NOF-C0635)
Product name: Semperguard® Xtra Lite
Date of issue: 22/06/15

GENERAL INFORMATION

Type: single-use disposable examination or protective glove
Marking: all information on dispenser box
Shape: ambidextrous – straight fingers
Material: Nitrile Butadiene Rubber (NBR)
Colour: lavender-blue
Inner: online chlorinated/powder free
Outer: no treatment
Cuff/Surface: rolled cuff/finger textured

Thickness: (double measured)	Finger: min. 0.14 mm	Palm: min. 0.12 mm	Cuff: min. 0.10 mm
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Residual powder:	≤ 2 mg / glove
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Force at break: [according to EN 455-2]	med. 6.0 N (during shelf life)
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Length:	median 240 mm
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Available Sizes:	S (6-7)	M (7-8)	L (8-9)	XL (9-10)
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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 455 ASTM D6319	EN 374-2: specified level 2 - AQL 1.5 level 3: AQL <0.65 (G1) level 2: AQL <1.5 (G1) level 1: AQL <4.0 (S4)	EN 374-3: Class 6 Sodium Hydroxide 40%
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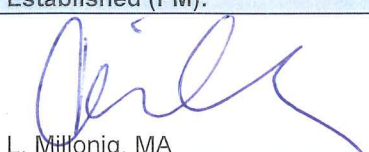
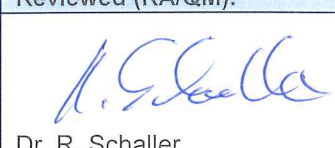
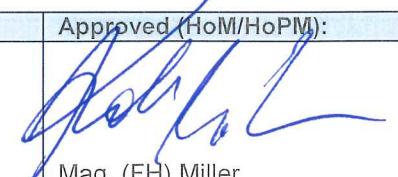
Conformity to food regulation: 1935/2004 

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):	Reviewed (RA/QM):	Approved (HoM/HoPM):
 L. Millonig, MA	 Dr. R. Schaller	 Mag. (FH) Miller