

Spec code: LOF-050NA-N-3CZ (LOF-C0150)
Product name: Sempercure® edition
Date of issue: 23/10/15

GENERAL INFORMATION

Type: single-use disposable examination or protective glove
Marking: all information on dispenser box
Shape: ambidextrous – straight fingers
Material: Natural Rubber Latex (NRL)
Colour: natural white
Inner: online chlorinated/powder free
Outer: no treatment
Cuff/Surface: rolled cuff/fingertip textured

Thickness: <small>(double measured)</small>	Finger: min. 0.22 mm	Palm: min. 0.20 mm	Cuff: min. 0.16 mm
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Residual powder: <small>[according to EN 455-3]</small>	≤ 2 mg / glove	Force at break: <small>[according to EN 455-2]</small>	med. ≥ 6.0 N (during shelf life)
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Length: <small>[according to EN 455-2]</small>	median 240 mm	Elongation: <small>[according to ASTM D3578]</small>	min. 650 % (before aging) / min. 500% (before aging)
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Available Sizes:	XS (5-6)	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 374-2: specified EN 374-3: Class 4
 EN 455 level 2 - AQL 1.5 Sodium Hydroxide 40%
 ASTM D3578 level 3: AQL <0.65 (G1)
 (except stress at 500% level 2: AQL <1.5 (G1)
 elongation) level 1: AQL <4.0 (S4)



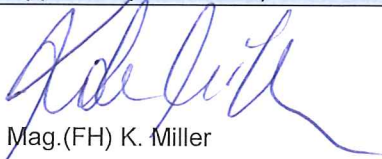
Conformity to food regulation: 1935/2004 

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

Established (PM):	Reviewed (RA/R&D):	Approved (HoM/HoPM):
 L. Millonig	 Dr. R. Schaller	 Mag.(FH) K. Miller