PRODUCT SPECIFICATION

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Spec code: LOF-050NA-N-3CZ (LOF-C0150)
Product name: Sempercare® 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: (double measured)	**Finger:** min. 0.22 mm	**Palm:** min. 0.20 mm	**Cuff:** min. 0.16 mm

Residual powder: [according to EN 455-3]	≤ 2 mg / glove	**Force at break:** [according to EN 455-2]	med. ≥ 6.0 N (during shelf life)
Length: [according to EN 455-2]	median 240 mm	**Elongation:** [according to ASTM D3578]	min. 650 % (before aging) / min. 500% (before aging)

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 level 2 - AQL 1.5	EN 374-3: Class 4
EN 455	level 3: AQL <0.65 (G1)	Sodium Hydroxide 40%
ASTM D3578 (except stress at 500% elongation)	level 2: AQL <1.5 (G1)	
	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