PRODUCT SPECIFICATION

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Spec code: NOF-035VB-N-3CZ (NOF-C0635)
Product name: Sempercare® nitrile skin²
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: Nitrile Butadiene Rubber (NBR)
Colour: violet blue
Inner: online chlorinated
Outer: no treatment
Cuff/Surface: rolled cuff/fingertip textured

Thickness: (double measured)	**Finger:** min. 0.14 mm	**Palm:** min. 0.12 mm	**Cuff:** min. 0.10 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 D6319]	min. 500 % (before aging) / min. 400% (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 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%

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/R&D):	Approved (HoM/HoPM):
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