

PRODUCT SPECIFICATION

Spec code: NOF-047RB-S-3CE (NOF-C0347 sterile)
Product name: Sempercure® nitrile sterile
Date of issue: 18/05/15

GENERAL INFORMATION

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

Thickness: <small>(double measured)</small>	Finger: min. 0.18 mm	Palm: min. 0.15 mm	Cuff: min. 0.10 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:	median 240 mm
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Available Sizes:	S (6-7)	M (7-8)	L (8-9)
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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.

Sterilisation: Gamma radiation with Cobalt-60. Minimum dose: 25 kGy (2.5 Mrad). Indicator (change colour from yellow to violet brown) placed on dispenser box and transport carton.

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 Is

Conformity to standards:

EN 420	EN 374-2: specified	EN 374-3: Class 6
EN 455	level 2 - AQL 1.5	Sodium Hydroxide 40%
ASTM D6319	level 3: AQL <0.65 (G1)	
EN 554, 556	level 2: AQL <1.5 (G1)	
	level 1: AQL <4.0 (S4)	

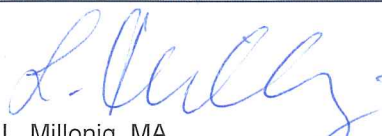
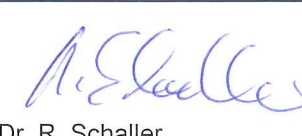
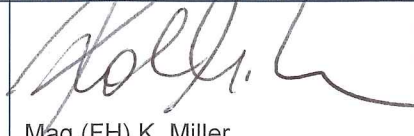
Conformity to food regulation: 1935/2004 

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 which may cause allergic reactions!

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