

PRODUCT SPECIFICATION

Spec code: NOF-030VB-N-3CZ
Product name: Semperguard® sapphire-blue
Date of issue: 01/06/2016

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: <small>(double measured)</small>	Finger: min. 0.10 mm	Palm: min. 0.10 mm	Cuff: min. 0.08 mm
Residual powder: <small>[according to EN 455-3]</small>	≤ 2 mg / glove		Force at break: <small>[according to EN 455-2]</small>
Length: <small>[according to EN 455-2]</small>	median 240 mm		Elongation: <small>[according to ASTM D6319]</small>
Available Sizes:	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 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)	
	level 2: AQL <1.5 (G1)	
	level 1: AQL <4.0 (S4)	

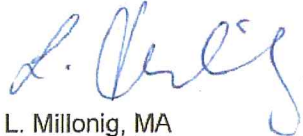


Conformity to food regulation: 1935/2004 

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/R&D):	Approved (HoM/HoPM):
 L. Millionig, MA	 Dr. R. Schaller	 P-E. Pap, MSc