

PRODUCT SPECIFICATION

Product name: sempercure® green
Spec code: NCF-035GR-N-3CZ
Date of issue: 14-Nov-2017

| | | |
|--------------|---|-----------------|
| Type | single use examination and disposable protective glove, non sterile | Available sizes |
| Labelling | all information on dispenser box | |
| Shape | ambidextrous - straight fingers | XS (5-6) |
| Material | Nitrile Butadiene Rubber (NBR) - [accelerator-free and latex-free] | S (6-7) |
| Colour | green | M (7-8) |
| Inner | polymer coated / powder free | L (8-9) |
| Outer | no treatment | XL (9-10) |
| Cuff/surface | rolled cuff/fingertip textured | |
| Storage life | 3 years | |

| Min. thickness [in mm] | Finger | Palm | Cuff |
|------------------------|--------|------|------|
| single measured | 0.07 | 0.06 | 0.05 |
| double measured | 0.14 | 0.12 | 0.10 |

| | Before aging | After aging | Testing method |
|------------------|--------------|-------------|----------------|
| Elongation | min. 500 % | min. 400 % | ASTM D6319 |
| Tensile strength | min. 14 MPa | min. 14 MPa | ASTM D6319 |

| | | |
|----------------------------------|----------------|----------------------|
| AQL (for pinholes) | ≤ 1.5 | EN 374-2 EN 455-1 |
| Residual powder / Powder content | ≤ 2 mg/glove | EN 455-3 |
| Force at break | median ≥ 6.0 N | EN 455-2 |
| Length | median 240 mm | EN 455-2 |

Storage instructions

Store according to ISO 2230:2002. Ensure that the area is kept 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 & quality certificates

| | |
|-------------------------------|--|
| Quality certification | ISO 9001 ISO 13485 ISO 14001 OSHAS 18001 |
| Conformity to directives | Personal Protective Equipment 89/686/EEC: Cat III for complex risks Medical Device Directive 93/42/EEC: Class I |
| Conformity to standards | EN 420 EN 455 1-4 EN ISO 374-1, EN 374-2, ISO 16523, EN 374-4 ASTM D6319 ASTM F1671 |
| Conformity to food regulation | 1935/2004 (EC) |
| labelling according to | ISO 15223 EN 420 EN ISO 374 |

Warning and reporting system

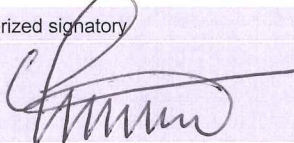
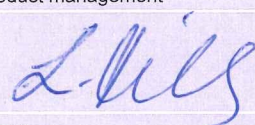
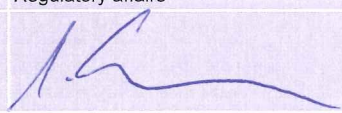
Potentially allergenic ingredients

not known

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. E-Mail: sempermed.complaints@semperitgroup.com or Tel.: +43 2630 310 ext. -510; Fax: -549

| | | |
|---|---|---|
| Authorized signatory | Product management | Regulatory affairs |
|  |  |  |
| C. Eichler | L. Millonig | J. Glantschnig |