

PRODUCT SPECIFICATION

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| Product name | Sempercure® nitrile aloe |
| Type | Single-use disposable examination and protective glove |
| Marking | all information on dispenser box |
| Shape | straight fingers, ambidextrous |
| Material | Nitrile Butadiene Rubber (NBR) powder-free |
| Colour | blue |
| Cuff / Surface | rolled rim / extra grip in fingertip area |

| Size | Length [according to EN 455-2] | Width [according to EN 455-2] | Article number |
|-----------|-----------------------------------|----------------------------------|----------------|
| XS (5-6) | med. 240 mm | med ≤ 80 | 8267 80641 |
| S (6-7) | med. 240 mm | med. 80 ± 10 | 8267 80643 |
| M (7-8) | med. 240 mm | med. 95 ± 10 | 8267 80645 |
| L (8-9) | med. 240 mm | med. 110 ± 10 | 8267 80647 |
| XL (9-10) | med. 240 mm | med. ≥ 110 | 8267 80649 |

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| Packaging / loading volume | Dispenser box (DB) XS, S, M, L (by weight) | 200 | pcs |
| | Dispenser box (DB) XL (by weight) | 180 | pcs |
| | Transport carton (TC) | 10 | DB |

| Packaging dimensions | width [mm] | length [mm] | height [mm] |
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| Dispenser box | 125 | 245 | 74 |
| Transport carton | 255 | 385 | 255 |

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| Thickness (double measured) | Palm: min. 0.10 mm (AQL 4.0) |
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| Residual powder [according to EN 455-3] | ≤ 2 mg / glove |
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| Force at break [according to EN 455-2] | med. 6.0 N (during shelf life) / med. 6.0 N (after challenge testing) |
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| Quality certification | ISO 9001, ISO 13485 | | |
| Conformity to guidelines | Medical Device Directive 93/42/EEC: CE Class I Personal Protective Equipment 89/686/EEC: CE cat. III In compliance with GMP rules (Good Manufacturing Practice) | | |
| Type examination done by | SATRA Technology Centre (notified body 0321) | | |
| Conformity to standards | EN 455 EN 420 | 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% |

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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. |
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Caution! This product contains accelerators which may cause allergic reactions!

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| Potentially allergenic ingredients: (For further information the actual version of the ingredients list is given on request.) | Dithiocarbamate type Zinc-Mercaptobenzothiazolate |
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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



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| Customer approval: |
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| Established (PM/DM1): <i>M. Kapeller</i> M. Kapeller MA | Reviewed (QM/DM): <i>B. Sebauer</i> DI (FH) B. Sebauer | Approved (HD/DM): <i>C. Elchler</i> DI C. Elchler |
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