

## Technical product specification

|                      |                                  |                                                                     |
|----------------------|----------------------------------|---------------------------------------------------------------------|
| <b>Product name</b>  | <b>semperguard vinyl comfort</b> | <b>Version / Index no:</b>                                          |
| <b>Spec code</b>     | <b>VCS-048CL-N-3CZ</b>           | semperguard vinyl comfort_VCS-048CL-N-3CZ_Version A_October 2024_EN |
| <b>Date of issue</b> | <b>08.10.2024</b>                |                                                                     |

### General information

|                        |                                                             |
|------------------------|-------------------------------------------------------------|
| <b>Type</b>            | single use disposable protective glove, non sterile         |
| <b>Labelling</b>       | information printed on dispenser box                        |
| <b>Shape</b>           | ambidextrous - straight fingers                             |
| <b>Material</b>        | Polyvinylchlorid (PVC) [not made with natural rubber latex] |
| <b>Colour</b>          | transparent                                                 |
| <b>Inside</b>          | polymer coated / powder free                                |
| <b>Outside</b>         | no treatment                                                |
| <b>Cuff / surface</b>  | rolled cuff / smooth                                        |
| <b>Shelf life</b>      | 3 - 5 years (subject to labelling)                          |
| <b>Available sizes</b> | S (6-7) M (7-8) L (8-9) XL (9-10)                           |

### Dimensions, physical properties and biocompatibility

|                                         |                                                                                                                                                                                                                        |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Glove length</b>                     | median $\geq 240$ mm (according to EN 455-2)                                                                                                                                                                           |
| <b>Minimum wall thickness</b>           | <i>at finger</i> 0.10 mm (double measured) / 0.05 mm (single measured)<br><i>at palm</i> 0.14 mm (double measured) / 0.07 mm (single measured)<br><i>at cuff</i> 0.08 mm (double measured) / 0.04 mm (single measured) |
| <b>Glove width</b>                      | according to EN 455-2: median S $80 \pm 10$ mm, M $95 \pm 10$ mm, L $110 \pm 10$ mm, XL $\geq 110$ mm                                                                                                                  |
| <b>Force at Break</b>                   | median $\geq 3.6$ N (during shelf life according to EN 455-2)                                                                                                                                                          |
| <b>Tensile Strength</b>                 | min. 9 MPa after aging (according to ASTM D5250)                                                                                                                                                                       |
| <b>Elongation at Break</b>              | min. 300% after aging (according to ASTM D5250)                                                                                                                                                                        |
| <b>Residual powder / Powder content</b> | $\leq 2$ mg (according to EN 455-2)                                                                                                                                                                                    |

### Performance requirement and inspection level

|                                     |                                                                                  |
|-------------------------------------|----------------------------------------------------------------------------------|
| <b>Freedom from holes (Barrier)</b> | AQL $\leq 1.5$<br>(as per EN 455-1, sampling in accordance with ISO 2859-1, G-1) |
|-------------------------------------|----------------------------------------------------------------------------------|

### Standards, guidelines & quality certificates

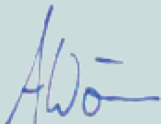
|                                  |                                                                                                                                                                       |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Quality certification</b>     | ISO 9001, ISO 13485, ISO 14001, ISO 45001                                                                                                                             |
| <b>Conformity to regulations</b> | - PPE Regulation (EU) 2016/425: Category I<br>- Regulation (EC) 1935/2004 on Food Contact Materials and Regulation (EU) 10/2011 on plastic materials for food contact |
| <b>Conformity to standards</b>   | EN ISO 21420, EN 455-1, EN 455-2, EN 455-3, ISO 2859-1, ASTM F1671                                                                                                    |

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| Spec code     | VCS-048CL-N-3CZ           | semperguard vinyl comfort_VCS-048CL-N-3CZ_Version A_October 2024_EN |
| Date of issue | 08.10.2024                |                                                                     |

## Instructions and additional statements

|                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Storage instruction                             | Store in original packaging in a dry and dark place at 10° C to 30° C. Refer to guidelines of storage of rubber products as described in ISO 2230:2002. Ensure that storage 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, such as sunlight and oxidizing agents. Storage above 30° C will lead to accelerated aging and should be avoided. |
| Cautionary statement and ingredient information | No allergenic ingredients known.<br>For further information, a list of substances contained in the glove is available upon request.                                                                                                                                                                                                                                                                                                                                               |
| Medical device vigilance and reporting system   | not applicable                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

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| Remark | Replaces all previous versions.<br>All standards references refer to the date of document issue. |
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