

Technical product specification

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|---------------|-------------------------------------|------------------------------------|
| Product name | PROTECTS HYGIENIC Vinyl powder free | Version / Index no: |
| Spec code | VCS-040CL-N-2EA | PROTECTS HYGIENIC Vinyl PF_Version |
| Date of issue | 28/02/2019 | C_February 2019_EN |

General information

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

Dimensions, physical properties and biocompatibility

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|----------------------------------|---|---|
| Glove length | S: min. 220 mm; M-XL: min. 230 mm (according to ASTM D5250) | |
| Minimum wall thickness | <i>at finger</i> | 0.08 mm (double measured) / 0.04 mm (single measured) |
| | <i>at palm</i> | 0.08 mm (double measured) / 0.04 mm (single measured) |
| | <i>at cuff</i> | not specified |
| Glove width | median S 80 ± 10 mm, M 95 ± 10 mm, L 110 ± 10 mm, XL ≥ 110 mm | |
| Force at Break | not specified | |
| Tensile Strength | min. 9 MPa after aging (according to ASTM D5250) | |
| Elongation at Break | min. 300% after aging (according to ASTM D5250) | |
| Residual powder / Powder content | ≤ 2 mg (according to ASTM D5250) | |

Performance requirements and inspection levels

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| Freedom from holes (Barrier) | AQL 4.0 (sampling in accordance with ISO 2859-1, G-1) |
| Dimensions and physical properties | not specified |

Standards, guidelines & quality certificates

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| Quality certification | ISO 9001, ISO 14001 |
| Conformity to directives and regulations | - PPE Regulation (EU) 2016/425: Category I - Food Contact Materials Regulation (EC) 1935/2004 and (EU) 10/2011 on plastic materials |
| Conformity to standards | EN 420 |

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Instructions and additional statements

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| 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, 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. For further information, a list of substances contained in the glove is available upon request. |

Reporting system

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| Medical device vigilance and reporting system | not applicable |
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| Remark | Replaces all previous versions. All standards references refer to the date of document issue. |
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