

Technical product specification

Product name	sempervelvet	Version / Index no:
Spec code	LLT-295RB-N-8CE / LLT-295PK-N-8CE	sempervelvet_Version F_February
Date of issue	03.02.2020	2020_EN

General information

Type	protective glove for general use
Labelling	information printed on packaging
Shape	anatomical
Material	Natural Rubber Latex (NRL)
Colour	blue or pink
Inside	flock lined
Outside	chlorinated
Cuff / surface	wave cut cuff / fish scale pattern
Shelf life	3 years
Available sizes	S (6-7) M (7-8) L (8-9) XL (9-10)

Dimensions, physical properties and biocompatibility

Glove length	median 300 ± 10 mm						
Minimum wall thickness	<table> <tr> <td><i>at finger</i></td> <td>not specified</td> </tr> <tr> <td><i>at palm</i></td> <td>0.40 ± 0.05 mm (single measured)</td> </tr> <tr> <td><i>at cuff</i></td> <td>not specified</td> </tr> </table>	<i>at finger</i>	not specified	<i>at palm</i>	0.40 ± 0.05 mm (single measured)	<i>at cuff</i>	not specified
<i>at finger</i>	not specified						
<i>at palm</i>	0.40 ± 0.05 mm (single measured)						
<i>at cuff</i>	not specified						
Glove width	median S 100 ± 5 mm, M 108 ± 5 mm, L 115 ± 5 mm, XL 123 ± 5 mm						
Force at Break	not specified						
Tensile Strength	≥ 10 MPa (before aging) / ≥ 7.5 MPa (after aging)						
Elongation at Break	≥ 500% (before aging) / ≥ 375% (after aging)						
Residual powder / Powder content	not specified						

Performance requirements and inspection levels

Freedom from holes (Barrier)	AQL ≤ 1.5 (sampling in accordance with ISO 2859-1, G-1)
Dimensions and physical properties	not specified

Standards, guidelines & quality certificates

Quality certification	ISO 9001
Conformity to regulations	<ul style="list-style-type: none"> - PPE Regulation (EU) 2016/425: Category I or III - Regulation (EC) 1935/2004 on Food Contact Materials
Conformity to standards	EN 420, EN ISO 374-1, EN 374-2, EN 16523-1, EN 374-4, EN ISO 374-5, ISO 2859-1

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Instructions and additional statements

Storage instruction	<p>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.</p>
Cautionary statement and ingredient information	<p>This product contains natural rubber latex which may cause allergic reactions, including anaphylactic responses.</p> <p>This product contains accelerators (Dithiocarbamate types, Zinc-mercaptobenzothiazol) not to be used in a hypersensitivity of these substances.</p> <p>For further information, a list of substances contained in the glove is available upon request.</p>

Reporting system

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