



## INSTRUCTION OF USE: Sinomer Kalt N

### Material information and manufacturer data

|                            |   |   |  |                   |   |  |
|----------------------------|---|---|--|-------------------|---|--|
| <b>Name, trade name</b>    | Sinomer Kalt N  |   |  |                   |  | <input checked="" type="checkbox"/> Medical Device |
| <b>Classification</b>      | <b>Classification:</b>  | Ila   | <b>Labelling:</b>  | CE 0483           |   | <input type="checkbox"/> Technical Device          |
| <b>Data</b>                | <b>Article No.:</b>   | A04<>   |  | <b>Basis UDI:</b> | 763029670101P   |  |
| <b>Variants</b>            | <b>Powder</b>   |   | <b>Liquid</b>  |                   | <b>Colours</b>  |  |
|                            | 500g, 1.000g, 5.000g  |   | 250ml, 500ml, 1.000ml, 2.500ml                                     |                   | Rosa, Clear, Rosa V   |  |
| <b>Allowed equipment</b>   | Can be applied to metal alloys or metal frameworks and underlaid with adhesive bond and opaquer. (Duropont Silan, Duropont Opaker), as well as combinable with metal clasps and artificial teeth.   |   |  |                   |   |  |
| <b>Manufacturer data</b>   | <b>SRN:</b>   |  | LI-MF-000000633  |                   |   |  |
|                            | <b>Anschrift:</b>   |   | NOVODENT Ets.,<br>Industriestrasse 32, 9487 Bendorf, Liechtenstein |                   |   |  |
| <b>General information</b> | For professional use only (dental technicians/dentists). Document product name and LOT no. Follow the instructions for use. All serious incidents occurring in relation to the product shall be reported to the manufacturer and the competent authority of the Member State. |   |  |                   |   |  |
| <b>Intended purpose</b>    | For the fabrication of prosthetic restorations in full and partial dentures   |   |  |                   |   |  |
| <b>Indication</b>          | For plugging and pressing technique as well as injection technique: Partial removable dentures and total dentures   |   |  |                   |   |  |
| <b>Contraindication</b>    | Avoid direct contact of non-polymerised material in the intraoral area. In case of hypersensitivity of the patient to any of the ingredients, refrain from use.   |   |  |                   |   |  |

### Use of the product

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| <b>Properties</b>   |
| Two-component denture material powder + liquid, recipe free of methyl methacrylate monomer and free benzoyl peroxide. According to current knowledge, this base material is toxicologically harmless and can be described as low allergy. For sensitised persons, the suitability of Sinomer cold N should be tested with a platelet in the mouth for approx. 72 hours.<br>After completion, the denture can be stored in warm water or olive oil (approx. 30°C) for another 24-48 hours to remove traces of monomer from the processing. |

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| <b>Environment of use</b>  | <b>Shelf life and storage instructions</b>   |
| <b>Bei Raumtemperatur Anwendbar. Von Zündquellen fernhalten.</b> | Avoid direct sunlight. Always keep containers closed. The shelf life is 3 Years. Do not use the product after the expiry date. Keep out of reach of children. Store at room temperature min. + 2°C, max. 25°C.   |
| <b>Material composition</b>                                      |  |
| <b>Powder</b>  | Polymethyl methacrylate  |
| <b>Liquid:</b>   | Oligomer, polyurethane dimethacrylate  |
| <b>Skin protection</b>   | Disposable gloves butyl rubber, layer thickness 0.7mm, penetration time (min) >480<br>Disposable gloves nitrile rubber, layer thickness 0.4mm, penetration time (min) >120<br>The exact penetration time must be obtained from the manufacturer of the protective gloves and must be observed. |
| <b>Transport</b>   | For regulations on the transport of the raw material, please refer to the Sinomer Kalt N safety data sheets.   |
| <b>Specifications</b>  | For specific product specifications, please refer to the Sinomer Kalt N technical data sheet.  |

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| <b>Regulatory information</b>   | <b>SN EN ISO 20795-1</b> |
| During polishing, small amounts of monomer may be released on the surface, which may cause skin sensitisation in sensitised (sensitive) patients. In case of irritation or known allergy to any of the ingredients, the product should not be used. |                          |

**Instructions for use**

|                       |  |              |                 |           |                 |                 |                    |           |
|-----------------------|--|--------------|-----------------|-----------|-----------------|-----------------|--------------------|-----------|
| <b>Mixing ratio</b>   | 1.1 - 1.3 parts by weight powder to 1 part by weight liquid.<br>(e.g. 1.1g - 1.3g powder to 1g liquid)   |              |                 |           |                 |                 |                    |           |
| <b>Polymerisation</b> | <b>Device</b>  | Pressure pot | <b>Pressure</b> | 4 – 6 bar | <b>Duration</b> | 15 – 20 Minuten | <b>Temperature</b> | 40 – 45°C |
| <b>Processing</b>     | <b>Preparation and use</b><br>The plaster model is to be insulated with a suitable insulation such as Seperator CC or HC Universal. Insulations containing formaldehyde should be avoided.   |              |                 |           |                 |                 |                    |           |
|                       | Artificial teeth should be roughened before use, undercut and wetted with acetone. Metal clasps, retentions, should be coated with a primer such as Duropont Silan to achieve an optimal hold and aesthetic effects.   |              |                 |           |                 |                 |                    |           |
|                       | The product (raw material), should be used at room temperature. Weigh the powder with the liquid using a scale and mix well for 30 seconds. Allow to bubble briefly (30-60 seconds) and mix again. Then pour the compound into the potting and place it immediately into the pressure pot. After polymerisation, the workpiece is removed from the pressure pot and ground, finished and polished according to the state of the art. |              |                 |           |                 |                 |                    |           |
|                       | <b>Note on polishing</b><br>Pre-polish with an emery mandrel or rubber attachment. Then polish with a pumice stone, a goat hair brush and a small polishing fork.<br><br>Caution: Artificial teeth can quickly lose their aesthetic appearance if heavily polished.<br><br>Polish carefully with a polishing fork. Auxiliaries such as approved polishing agents for dental acrylics can be used.                                    |              |                 |           |                 |                 |                    |           |










**Liability notice**

The information is based on the current state of our knowledge, but does not constitute a guarantee of product properties and does not establish a contractual legal relationship. The product is normally delivered stabilised. However, it may polymerise under heat development if the storage time and/or storage temperature are significantly exceeded. No liability is accepted for damage resulting from failure to observe the instructions for use and the area of application. This also applies if the product is mixed or processed together with products from competitors.

**Contact details of the manufacturer**

|                     |   |  |             |               |                   |  |  |
|---------------------|---|--|-------------|---------------|-------------------|--|--|
| <b>Address:</b>     | NOVODENT Ets., Industriestrasse 32, 9487 Bendern, Liechtenstein   |  |             |               |                   |  |  |
| <b>Contact:</b>     | <b>Phonel.:</b>   | +423 377 1500  | <b>Fax:</b> | +423 377 1509 | <b>E-Mail:</b>    | <a href="mailto:frontoffice@novodent.com">frontoffice@novodent.com</a> |  |
| <b>Websites::</b>   | <b>Webshop:</b>   | <a href="http://www.novodent.dental">www.novodent.dental</a> |             |               | <b>Main page:</b> | <a href="http://www.novodent.com">www.novodent.com</a>                 |  |
| <b>SSCP Rapport</b> | <a href="https://sscp.novodent.com/prothesenkunststoffe.pdf">https://sscp.novodent.com/prothesenkunststoffe.pdf</a> |  |             |               |                   |  |  |

**Note about the symbols** ⓘ

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|---|--|---|--|--|--|
| <b>LOT</b>  | <input checked="" type="checkbox"/> Lot/Batch No.                        |  | <input checked="" type="checkbox"/> Manufacturer         | <b>UDI</b>   | <input checked="" type="checkbox"/> Unique Device Identification  |
|  | <input checked="" type="checkbox"/> Expiry date                          |  | <input checked="" type="checkbox"/> Storage temperatures |  | <input checked="" type="checkbox"/> Observe operating instructions   |
| <b>REF</b>  | <input checked="" type="checkbox"/> Articulenumber                       |  | <input type="checkbox"/> Protection from sunlight        | <b>MD</b>  | <input checked="" type="checkbox"/> Medical Device *   |
|  | <input checked="" type="checkbox"/> Attention (GHS)                      |  | <input type="checkbox"/> Danger Flammable (GHS)          |  | <input checked="" type="checkbox"/> Do not reuse   |
| <b>SRN</b>  | <input checked="" type="checkbox"/> Single Registration Number (EUDAMED) |   |  | <b>CE</b>  | <input checked="" type="checkbox"/> MP- European conformity *  |

ⓘ Symbols used on the labelling of this product are marked with . \*Not applicable for non-medical products