1. Purpose
The purpose of this specification is to determine the conditions which must be fulfilled by Optitemp Automix – a bis-acrylate composite material – before releasing it for despatch. This specification is one of the registration documents and is used as a reference document when contacting the purchasers.

2. Product Characteristics
Optitemp Automix is a bis-acrylate composite material which is used in dentistry for the preparation of temporary crowns, bridges, facets, inlays and onlays using the swage method. It comes in long term contact with human tissues.

3. Abbreviations
KRO Clinical and Registration Department
OKJ Quality Control Department
OVD Internal Documentation Department
PVJ Quality Management Representative
RUJKJ Quality Management Department Head
RVV Research and Development Department Head
SOP standard operation procedure
SP specification
ZP test procedure

4. Description
4.1 Product Name
OPTITEMP Automix
bis-acrylate composite material

4.2 Material Form, Colour Shades
Optitemp Automix is a homogeneous composite paste of heavy viscosity, in the A2 VITA shade.

4.3 Package Size and Description
OPTITEMP Automix – a bis-acrylate composite material:
78 gr. of paste in a cartridge and 15 application cannulas, all enclosed together with an instruction sheet in a folded paper box.

OPTITEMP Automix – application gun:
1 application gun and 15 application cannulas, all enclosed together with a graphic instruction sheet in a folded paper box.

OPTITEMP Automix – application needles:
15 application cannulas, enclosed in a PE bag with a cutter.

4.4 Collection of Samples
According to SOP 10.1/7, par. 5.1.

4.4.1 Number of counter-samples
1 package of each manufactured batch.

4.5 The Product Must Conform to the Following Requirements
4.5.1 Contents of the original package
OPTITEMP Automix:
78 gr. of paste in A2 shade: min. 73.5 gr.

4.5.2 Statistical product check
Conforms to SOP 10.1/7.
4.5.3 Other parameters

<table>
<thead>
<tr>
<th>Tested property</th>
<th>Theory</th>
<th>Tested according to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting time</td>
<td>max. 5:00 min.</td>
<td>ZP 171412</td>
</tr>
<tr>
<td>Absorption</td>
<td>max. 50.0 μg/mm³</td>
<td>ZP 171412</td>
</tr>
<tr>
<td>Solubility</td>
<td>max. 7.5 μg/mm³</td>
<td>ZP 171412</td>
</tr>
<tr>
<td>Bending strength</td>
<td>min. 50.00 MPa</td>
<td>ZP 171412</td>
</tr>
</tbody>
</table>

4.6 Storage Conditions
To be stored in a dry and dark place at 5–23 °C, in a well sealed internal package. Protect from temperatures exceeding 25°C.

4.7 Shelf Life
2 years

5. Related Documents
- SOP 5.1/2 Rules for preparation of specifications of finished products
- SOP 10.1/7 Rules for statistical check of products placed in inner packaging and for statistical check of finished products
- ZP 171412 Optitemp Automix A2
- CSN EN 1641 Dentistry – Medical devices for dentistry – Materials

6. Revisions
Modifications to this specification are provided by the UJKJ manager according to SOP 5.1/2

6.1 Revision Procedure

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<thead>
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<th>Description</th>
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<th>Revision</th>
<th>Date of issue</th>
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</thead>
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This specification replaces:

Name and Surname, position | Signature | Date
Prepared by:
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Approved by: Mgr. Jaroslav Adolf, RUJKJ
Released by: Mgr. Jaroslav Adolf, PVJ
Issued by:
Ing. Tamara Stránská, OVD, Manager

In effect from: the date of issue