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
   JKJ ...................... Quality Assurance and Quality Control
   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 g of paste in a cartridge and 15 application tips, all enclosed together with an instruction sheet in a folded paper box.
   OPTITEMP Automix – application gun:
   1 application gun and 15 application tips, all enclosed together with a graphic instruction sheet in a folded paper box.
   OPTITEMP Automix – application needles:
   15 application tips, enclosed in a PE bag with a cutter.

4.4 Collection of Samples: According to SOP 10-104, 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: Conforms to SOP 10-104.
4.5.2 Other parameters:

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<th>Theory</th>
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<tr>
<td>Appearance</td>
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<td>Setting time</td>
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<tr>
<td>Bending strength</td>
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**4.6 Storage Conditions:**
To be stored in a dry and dark place at 5°C to 23°C in a well sealed internal package.

**4.7 Shelf Life:** 2 years

**5. RELATED DOCUMENTS**
- SOP 05-101 Rules for preparation of controlled documentation Level III.
- SOP 10-104 Rules for take-off of the control samples and raw material
- ZP 171412 Optitemp Automix A2
- CSN EN 1641 Dentistry - Medical devices for dentistry - Materials

**6. REVISIONS**
Modifications to this specification are provided by the JKJ Manager according to SOP 05-101.

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**7. APPROVING**
Czech version was approved in the MasterControl 28.1.2019.