



## TECHNICAL DATA SHEET

**Product:** Alpha-Dent<sup>®</sup> One-Step Bracket Adhesive and Primer

**Product Description:** Alpha-Dent<sup>®</sup> One-Step Bracket Adhesive is a Paste-Primer orthodontic adhesive designed to bond metal, ceramic and plastic brackets. The unique filler and primer combination used produces an ideal bond and a smooth tacky viscosity minimizing bracket flotation.

**Indications for Use:** Alpha-Dent<sup>®</sup> One-Step Bracket Adhesive is a Paste-Primer orthodontic adhesive designed to bond metal, ceramic and plastic brackets to enamel.

**Appearance:** Medium-viscosity white paste and straw-colored liquid primer.

**Curing Mechanism:** Self cured with a paste and a primer.

**Shelf-Life:** 30 months.

**Filler Type:**

<b>Paste:</b>	
Quartz and silica	
Filler % by Volume	56
Filler Particle Range, microns	0.01– 5
Average Filler Particle Size, microns	4.65
<b>Primer:</b>	
No filler	

**Main Composition:**

<b>Paste:</b>	<b>% w/w</b>
Inorganic filler	60 – 80
Bis-GMA	10 – 30
Comonomer Diluent	< 10
Colorant	< 1
Inhibitor	< 1
Initiator	< 1
<b>Primer:</b>	<b>% w/w</b>
Methacrylate & bisacrylate monomers	60 – 80
Acrylic Polymer	10 – 20
Bis-GMA	5 – 15
Accelerator	< 5
Inhibitor	< 1

**Physical /Mechanical Properties: (Typical Values)**

Working Time, seconds at 23 °C	60
Setting Time, seconds at 37 °C	75
Bond Strength, Bracket - Enamel, MPa	12.5




**Regulatory Classification:**

This product is in conformity with the following standard(s) or other normative documents:

International Standard ISO/TS 11405:2015 Dental Materials-Testing of Adhesion to Tooth Structure  
Code of Federal Regulations, 21 CFR Part 820 – Medical Device Quality System Regulation

**Signature/Date:**

 / 10/18/18

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ISO 13485

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Associated Documents: DCN 1423, 1625, 1876, 3041, 3684, 4880, 6322