



TECHNICAL DATA SHEET

Product: Alpha-Dent® Light Cure Bonding Adhesive

Product Description: Alpha-Dent® Light Cure Bonding Adhesive is a versatile adhesive that is fast and easy to apply, and offers excellent bond strengths to dentin and enamel.

Indications for Use: Alpha-Dent® Light Cure Bonding Adhesive is a dental adhesive designed to bond light cured composite restorative materials to enamel and dentin.

Appearance: A low-viscosity liquid with color ranging from clear colorless to clear pale yellow.

Curing Mechanism: Light cured by applying an external energy activated Dental Blue Light with minimum output 600mW/cm² and 400 to 500 nanometers.

Shelf-Life: 30 months

Filler Type: None

Main Composition (%w/w):

Bis-GMA	18 – 28
Comonomers	60 – 80
Adhesive Monomer	< 5
Photoinitiator	< 1
Stabilizer	< 1

Physical /Mechanical Properties: (Typical Values)

Depth of Cure, mm (actual)	6.0
Bond Strength to Dentin, MPa	15
Bond Strength to Enamel, MPa	19.9

Regulatory Classification:

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

- International Standard ISO/ST 11405:2015 Dental Materials-Testing of Adhesion to Tooth Structure
- European Standard EN 1641:2009 – Medical Devices for Dentistry – Materials
- Code of Federal Regulations CFR 21 Part 820 – Medical Device Quality System Regulation
- Code of Federal Regulations CFR 21 Part 872.3200 Resin tooth bonding agent

Signature/Date: John Pontikis / 10/18/18

Name: John Pontikis
Position: Management Representative