



# TECHNICAL DATA SHEET

**Product:** Alpha-Dent® Light Cure Hybrid Composite

**Product Description:** Alpha-dent® Light Cure Composite Restorative Material with a Bis-GMA polymeric matrix and a 56% by volume blend of inorganic radiopaque fillers with particle range from 0.02 to 4 microns.

**Indications for Use:** Alpha-dent® Light Cure Composite Restorative Material is contraindicated on patients with a history of severe allergic reaction to methacrylate resins.

**Appearance:** A thick homogeneous paste available in all Vita® Shades.

**Curing Mechanism:** Light cured by applying an external energy activated Dental Blue Light with minimum output 600 mW /cm<sup>2</sup> and wavelength 400 – 500 nanometers.

**Shelf-Life:** 30 months

**Filler Type:** Barium glass and Silica

Filler % by Volume:	56
Filler Particle Range, μ:	0.02 - 4
Average Filler Particle Size, μ:	2

**Main Composition (%w/w):**

Blend of radiopaque fillers	60 – 80
Bis-GMA	10 – 20
Comonomer diluents	5 - 15
Photoinitiator	< 1
Stabilizer	< 1
Colorant	< 1

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

Compressive Strength, MPa	225
Diametral Strength, MPa	47
Flexural Strength, MPa	95
Water Absorption, μg / mm <sup>3</sup>	20
Water Solubility, μg / mm <sup>3</sup>	1
Depth of cure, mm/2	2.5
Radiopacity, 1 mm disk	equivalent to 1 mm aluminum

**Regulatory Classification:**

This product is in conformity with the following standard(s) or other normative documents:  
International Standard ISO 4049: 2019 Dentistry – Polymer-Based Restorative Materials  
ANSI/ADA Specification No. 27: 2016- Resin Base Filling Material  
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 – Dental Devices, Section 3690 Tooth Shade Resin Material

**Signature/ Date:** John Pontikis / 6/5/19

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**Position:** Management Representative