

ISO 13485

## TECHNICAL DATA SHEET

**Product:** Alpha-Bond® SE Light Cure Self Etch Adhesive

**Product Description:** Alpha-Bond<sup>®</sup> SE is a 7<sup>th</sup> generation self-etch adhesive formulated to bond to multiple

substrates for both direct and indirect bonding procedures. It is a universal adhesive that has the bond strength and durability of a total-etch adhesive while eliminating

the etching step.

**Indications for Use:** Adhesive formulated to bond to multiple substrates for both direct and indirect

bonding procedures.

**Appearance:** Clear liquid

**Curing Mechanism:** Light cured by applying an external energy activated Dental Blue Light with a

minimum output of 600 mW/cm<sup>2</sup> and wavelength of 400 to 500 nanometers.

**Shelf-Life:** 24 months

Main Composition: Components (%w/w)

Photo initiator <1
Water <10
Blend of Methacrylate Monomers <30
Adhesive Monomer (36%) in acetone <30

**Physical /Mechanical Properties:** 

Bond Strength to Dentin, MPa: 37

## **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. European Standard EN 1641:2009 – Medical Devices for Dentistry – Materials.

Code of Federal Regulations CFR 21 Part 820 – Medical Device for Quality System Regulation.

Code of Federal Regulations CFR 21 Part 872.3200 – Resin Tooth Bonding Agent.

Signature/ Date: \_\_\_\_\_/ 10/24/18

Name: John Pontikis

**Position:** Management Representative

DENTAL TECHNOLOGIES, INC.

6901 N. HAMLIN AVENUE LINCOLNWOOD, ILLINOIS 60712 USA Page 1 of 1 TDS-028 Rev.002 Associated Documents: NR 1851, DCN 4880, 6335