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ISO 13485

# TECHNICAL DATA SHEET

**Product:** Alpha-Core<sup>®</sup> DC Dual Cure Resin Based Composite

**Product Description:** Alpha-Core® DC is a highly filled radiopaque, dual cure composite in an Automix

Delivery System designed specifically for core build-ups and cementation of posts and pins. The material exhibits ideal mechanical properties with high compressive

and tensile strength yet maintains a dentin-like feel while cutting.

**Indications for Use:** Alpha-Core<sup>®</sup> DC is designed specifically for core build-ups and cementation of posts

and pins.

**Appearance:** Catalyst: Opaque white paste

Base: Opaque blue or natural (A2) shade paste.

Curing Mechanism: Dual-cured:

- Self-cured by mixing base and catalyst together.

- 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 nm.

**Shelf-Life:** 36 months

**Filler Type**: Blend of inorganic fillers.

Filler % by Volume: 48.61 Filler Particle Range,  $\mu$ m: 0.02 – 5.0 Average Filler Particle Size,  $\mu$ m: 3.14

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

| Inorganic Fillers              | 65 - 75 |
|--------------------------------|---------|
| Blend of Methacrylate Monomers | 25 - 35 |
| Initiator                      | < 1     |
| Inhibitor                      | < 1     |
| Acelerator                     | < 1     |
| Photoinitoator                 | < 1     |
| UV Absorber                    | < 1     |
| Colorants                      | < 1     |

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

| Working Time (Blue Shade) at 23 °C, seconds    | 110 |
|--|-----|
| Working Time (Natural Shade) at 23 °C, seconds | 110 |
| Setting Time (Blue Shade) at 37 °C, seconds    | 135 |
| Setting Time (Natural Shade) at 37 °C, seconds | 135 |
| Depth of Cure (Blue shade) at 20 sec, mm/2     | 1.6 |
| Depth of Cure (Blue shade) at 40sec, mm/2      | 1.9 |
| Depth of Cure (Natural shade) at 20 sec, mm/2  | 2.0 |
| Depth of Cure (Natural shade) at 40 sec, mm/2  | 2.6 |
| Flexural Strength, MPa                         | 143 |

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 $\begin{array}{lll} \text{Diametral Tensile Strength, MPa} & 39 \\ \text{Compressive Strength, MPa} & 296 \\ \text{Water Sorption, } \mu\text{g/mm}^3 & 17.7 \\ \text{Water Solubility, } \mu\text{g/mm}^3 & 1.8 \\ \text{Color Stability} & \text{Stable} \\ \text{Radio-opacity, compared to 1mm thick Aluminum} & 1.0 \\ \end{array}$ 

### **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-Based Filling Materials European Standard BS 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: \_\_\_\_\_\_/ 6/5/19

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**Position:** Management Representative