



# TECHNICAL DATA SHEET

<b>Product:</b>	Alpha III™ Nano Light Cure Nano-Hybrid Composite																				
<b>Product Description:</b>	Alpha III™ NANO is a light cure, Bis-GMA resin-based nano-hybrid composite containing fluorescence to provide duplication of the natural tooth surface. Alpha III™ NANO consists of 62.63% by volume of specifically synthesized inorganic fillers which range in particle size from 0.18 micron to 2 micron that provide exceptional wear resistance and radiant polishability. Alpha III™ NANO is available in 6 Vita® shades (A1, A2, A3, A3.5, B1, B2). All shades are radio-opaque for easy identification.																				
<b>Indications for Use:</b>	Alpha III™ NANO is recommended for use in all anterior and posterior restorations.																				
<b>Appearance:</b>	A homogeneous paste available in six Vita® and all shades are radio-opaque for easy identification.																				
<b>Curing Mechanism:</b>	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.																				
<b>Shelf-Life:</b>	30 months																				
<b>Filler Type:</b>	Barium-alumino-boro-fluorosilicate glass and amorphous silica.																				
	<table border="0"> <tr> <td>Filler % by Volume</td> <td>62</td> </tr> <tr> <td>Filler Particle Range (μ)</td> <td>0.18 - 2</td> </tr> <tr> <td>Average Filler Particle Size (μ)</td> <td>0.7</td> </tr> </table>	Filler % by Volume	62	Filler Particle Range (μ)	0.18 - 2	Average Filler Particle Size (μ)	0.7														
Filler % by Volume	62																				
Filler Particle Range (μ)	0.18 - 2																				
Average Filler Particle Size (μ)	0.7																				
<b>Main Composition (%w/w):</b>																					
	<table border="0"> <tr> <td>Filler</td> <td>64 – 84</td> </tr> <tr> <td>Bis-GMA</td> <td>6 – 18</td> </tr> <tr> <td>Comonomers</td> <td>8 – 21</td> </tr> <tr> <td>Preservative</td> <td>&lt; 1</td> </tr> <tr> <td>Colorant</td> <td>&lt; 1</td> </tr> <tr> <td>UV light absorber</td> <td>&lt; 1</td> </tr> <tr> <td>Photoinitiator</td> <td>&lt; 1</td> </tr> </table>	Filler	64 – 84	Bis-GMA	6 – 18	Comonomers	8 – 21	Preservative	< 1	Colorant	< 1	UV light absorber	< 1	Photoinitiator	< 1						
Filler	64 – 84																				
Bis-GMA	6 – 18																				
Comonomers	8 – 21																				
Preservative	< 1																				
Colorant	< 1																				
UV light absorber	< 1																				
Photoinitiator	< 1																				
<b>Physical /Mechanical Properties:</b>																					
	<table border="0"> <tr> <td>Water Sorption, μg/mm<sup>3</sup></td> <td>20</td> </tr> <tr> <td>Water Solubility, μg/mm<sup>3</sup></td> <td>0.60</td> </tr> <tr> <td>Diametral Tensile Strength, MPa</td> <td>50</td> </tr> <tr> <td>Compressive Strength, MPa</td> <td>275</td> </tr> <tr> <td>Flexural Strength, MPa</td> <td>95</td> </tr> <tr> <td>Radiopacity, 1 mm disk</td> <td>equivalent to 1 mm aluminum</td> </tr> <tr> <td>Polymerization shrinkage, %</td> <td>2.6</td> </tr> <tr> <td>Depth of cure, mm/2:</td> <td></td> </tr> <tr> <td>    Light shades (A1, A2, A3, B1, B2)</td> <td>2.5</td> </tr> <tr> <td>    Dark shades (A3.5)</td> <td>2.3</td> </tr> </table>	Water Sorption, μg/mm <sup>3</sup>	20	Water Solubility, μg/mm <sup>3</sup>	0.60	Diametral Tensile Strength, MPa	50	Compressive Strength, MPa	275	Flexural Strength, MPa	95	Radiopacity, 1 mm disk	equivalent to 1 mm aluminum	Polymerization shrinkage, %	2.6	Depth of cure, mm/2:		Light shades (A1, A2, A3, B1, B2)	2.5	Dark shades (A3.5)	2.3
Water Sorption, μg/mm <sup>3</sup>	20																				
Water Solubility, μg/mm <sup>3</sup>	0.60																				
Diametral Tensile Strength, MPa	50																				
Compressive Strength, MPa	275																				
Flexural Strength, MPa	95																				
Radiopacity, 1 mm disk	equivalent to 1 mm aluminum																				
Polymerization shrinkage, %	2.6																				
Depth of cure, mm/2:																					
Light shades (A1, A2, A3, B1, B2)	2.5																				
Dark shades (A3.5)	2.3																				



**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 Dentistry – Resin-Based Filling Materials  
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

**Name:**

John Pontikis

**Position:**

Management Representative

ISO 13485