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ISO 13485

TECHNICAL DATA SHEET

Product: Alpha-Flow[®] Light Cure Flowable Composite

Product Description: Alpha-Flow is a radiopaque fluoride containing light cure resin-based micro-hybrid

flowable composite. The organic matrix is based on Bis-GMA resin and contains a 38% by volume blend of inorganic fillers with particle sizes ranging from 0.02 – 0.70 microns. This special combination provides a material with extreme versatility for use in a wide range of procedures, including Class III and V cavity figurations

and small Class I and II restorations.

Indications for Use: For blocking out small undercuts, fill tunnel preps, marginal defect repairs, repair

composite and ceramic veneers and re-conform temporary restorations.

Appearance: Opaque, flowing paste.

Shades: A1, A2, A3, A3.5, B1, B2, and Universal Opaquer

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

minimum output of 600 mW/cm² and wavelength 400 to 500 nanometers.

Shelf-Life: 30 months

Filler Type: Radio-opaque barium-alumino-boro-fluorosilicate glass

Filler % by Volume: 38

Filler Particle Range (μ m): 0.02 – 0.70 Average Filler Particle Size (μ m): 0.65

Main Composition (%w/w):

Component: % w/w Inorganic filler 55-65 Blend of methacrylate and dimethacrylate monomers 35-45 Initiators <1 Inhibitor <1 UV stabilizers <1 Colorants <1

Physical /Mechanical Properties:

Sensitivity to ambient light:

No change in consistency after

60 sec. exposure to test light.

Flexural strength, MPa: 110 (typical value)
Water absorption, µg/mm³: 17 (typical value)
Water solubility, µg/mm³: 1.3 (typical value)

Shade: Matches Vita Shade Guide

Color stability: Stable

Radio-opacity, 1 mm disk: ≥1 mm thickness of Aluminum

Depth of Cure, mm/2:

Light Shades (A1, A2, A3, B1, B2)

Dark Shades (A3.5, Opaquer)

2.3 (typical value)

2.0 (typical value)



Regulatory Classification:

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

Code of Federal Regulations CFR 21 Part 820 Medical Device Quality System Regulation Code of Federal Regulations CFR 21 Part 872, §872.3690 Tooth Shade Resin Material International Standard ISO 4049:2019 Dentistry – Polymer-Based Restorative Materials ADA Specification No. 27/ Direct Filling Resins: 2016

Signature/ Date: ______/ 6/5/19

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Position: Management Representative

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