



TECHNICAL DATA SHEET

Product: Alpha-Dam® Light Cure Gingival Dam

Product Description: Alpha-Dam® Light Cure Gingival Dam serves as a barrier for in-office whitening treatments. The material cures quickly and evenly, while maintaining low exotherms (temperature rise of less than 12°C) to ensure patient comfort.

Indications for Use: Alpha-Dam® Light Cure Gingival Dam is designed to serve as a barrier for in-office whitening treatments.

Appearance: Homogenous, clear blue gel.

Curing Mechanism: Light cured by applying an external energy activated Dental Blue Light with minimum output of 600mW/cm² and wavelength of 400 to 500 nanometers.

Shelf-Life: 30 months

Filler Type: None

Main Composition (%w/w):

Blend of multifunctional monomers	85 – 95
Thickener	5 – 15
Colorant	< 1
Photoinitiator	< 1
Accelerator	< 1
Inhibitor	< 1

Physical /Mechanical Properties: (Typical Values)

Color (Pantone® Color Guide)	315C – 308C
Depth of Cure, mm/10sec.	7
Consistency, mm	0.4

Regulatory Classification:

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

- 21 CFR Part 820 – Medical Device Quality System Regulation
- 21 CFR Part 872.6300 - Rubber Dam and Accessories

Signature/ Date:

John Pontikis / 10/25/18

Name:

John Pontikis

Position:

Management Representative