

DECLARATION OF CONFORMITY

OPALDAM™, OPALDAM™ GREEN



Ultradent Products Inc., 505 West Ultradent Drive (10200 South), South Jordan, UT, 84095 has evaluated this product by using the Conformity Assessment Procedure of Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, and confirms that this product is compliant with the General Safety and Performance Requirements of Annex I of the Regulation (EU) 2017/745. Technical documentation is located in the Regulatory Affairs Department.

Identified Legislations:	<i>Regulation (EU) 2017/745 – European Parliament and of the Council of 5 April 2017 on medical devices</i>
EC Representative:	Ultradent Products GmbH Am Westhover Berg 30 51149 Cologne Germany
Device Classification:	This product system is classified as a Class I medical device according to Regulation (EU) 2017/745, Annex VIII, Chapter III, Section 5.1, Rule 5.
Intended Purpose:	OpalDam and OpalDam Green are unique, light-reflective, passively adhesive (sealing) light cured resins. Their methacrylate base is designed with adequate strength to maintain a barrier, yet removes easily from embrasures and undercuts. The contrasting green color of OpalDam Green shows its location on the gingiva and teeth for more effective coverage.
UMDNS Code:	11155 - Rubber dams, Dental
GMDN Code:	45004 – Rubber dam, Non-latex
EMDN Code:	Q019002 – Dental Device, Rubber Dam and Hooks
Basic UDI-DI:	0883205-TF279BU
Eudamed SRN:	DE-AR-000006666, DE-IM-000010855, US-MF-000013697
Common Specifications:	N/A
Model Numbers:	324-U, 325-U, 326-U, 1824-U, 1825-U, 1826-U

DECLARATION OF CONFORMITY

OPALDAM™, OPALDAM™ GREEN



Images:



This Declaration of Conformity is issued under the sole responsibility of the manufacturer and is in force as long as the following certificate is valid:

DIN EN ISO 13485:2021 Reg.-No. 44 221 090234 valid until 05 March 2029

Adam Black, RAC
Director - Regulatory Affairs & Clinical Operations

23 Feb 2026

Date

State of Utah, County of Salt Lake
Subscribed and sworn to before me on this

23 day of February 2026
By Adam Black

Amy Henderson-Nielson, Notary Public

