


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.

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
CND Code:	Q019002 – Dental Devices, Rubber Dam and Hooks
Basic UDI-DI:	0883205-TF279BU (OpalDam Green), 0883205-TF054B2 (OpalDam)
Eudamed SRN:	Not applicable at this time
Model Numbers:	324, 324-U, 325, 325-U, 326, 326-U, 1824, 1824-U, 1825, 1825-U, 1826, 1826-U
Images:	


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

ISO 13485:2016 Certificate 19-1613-M/19-16112-Q valid through 02 August 2023

DIN EN ISO 13485:2016 Reg.-No. 44 221 090234 valid through 05 March 2023

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Adam Black
Regulatory Affairs Manager

15 APR 2021

Date

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

15 day of April 2021
By Adam Black



Notary Public

 Amy Henderson-Nielson
NOTARY PUBLIC - STATE OF UTAH
My Comm. Exp. 08/03/2024
Commission # 713340