

DECLARATION OF CONFORMITY

ORASEAL CAULK AND PUTTY

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, Rule 2.1.
Intended Purpose:	<p>OraSeal Caulking is used to seal rubber dams to optimize tissue isolation; i.e., irritating seepage of strong peroxide solutions during power bleaching or hydrofluoric acid during porcelain etching, etc. It is excellent for repair of rubber dam leakage resulting from difficult adaptation associated with endodontic procedures, small perforations, and areas where fixed partial denture connectors prevent adequate seal.</p> <p>OraSeal Putty is used to block out undercuts associated with large gingival embrasures, implant bars, precision attachments, or fixed partial denture pontics during impression making procedures. Its heavier body prevents displacement during intraoral pick-up of anchoring attachments with autopolymerizing resins.</p>
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-TF049B9
Eudamed SRN:	N/A
Model Numbers:	351-, 352-, 353-, 354-, 355-

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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

Adam Black
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 20 21
By Adam Black

Amy Henderson-Nielson
Notary Public

