

DECLARATION OF CONFORMITY

ULTRAPAK KNITTED RETRACTION CORD

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:	Ultrapak cord is to be used for gingival retraction and control of sulcular fluid.
UMDNS Code:	16352; Gingival Retraction Cords
GMDN Code:	16352; Retraction kit, gingival
EMDN Code:	Q010204 – Retraction Wires and Gingival Retractors
Basic UDI-DI:	0883205-TF028AZ
Eudamed SRN:	US-MF-000013697
Common Specifications:	Not applicable
Model Numbers	REF/UP: 9330, 9331, 9332, 9333, 9334, 9335, 9336
Images:	

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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

A handwritten signature in blue ink, appearing to read 'Adam Black'.

Adam Black, RAC

Director - Regulatory Affairs & Clinical Operations

24 feb 2026

Date

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

24 day of February 2026

By Adam Black

A handwritten signature in blue ink, appearing to read 'Amy Henderson-Nielson'.

Notary Public

