

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.

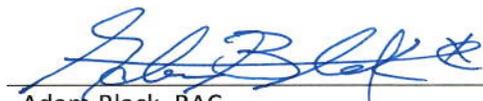
EC Representative:	Ultradent Products GmbH Am Westhover Berg 30 51149 Cologne Germany
Device Classification:	This product system is classified as a Class I medical device according to Regulation (EU) 2017/745, Annex VIII, Chapter III, Section 5.1, Rule 5.
Intended Purpose:	Ultrapak cord is to be used 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
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 certificates are valid:

ISO 13485:2016 Certificate 19-1612-Q valid through 15 Feb 2026
acc. to ISO 13485:2016 Certificate 19-1613-M valid through 15 Feb 2026



Adam Black, RAC

Senior Manager – Regulatory Affairs

05 September 2023

Date

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

5 day of September 2023

By Adam Black



Notary Public

