ULTRADENT PRODUCTS, INC.

DECLARATION OF CONFORMITY

TIPS

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 5.2, Rule 5.
Intended Purpose:	The Tips are intended to facilitate the delivery or extraction of fluids or dental chemistries into or out of the oral cavity.
UMDNS Code:	11160 Dental hand instrument
GMDN Code:	60366, Dental material injection cannula, single-use
CND/EMDM Code:	Q019006 - Dental Material Application Tips and Brushes, Single-Use
Basic UDI-DI:	0883205-TF032AQ
Eudamed SRN:	DE-AR-000006666, DE-IM-000010855, US-MF-000013697
Model Numbers:	5479, 5481, 5482
Images:	 Capillary Tips

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 02 Aug 2023
DIN EN ISO 13485:2016 Reg.-No. 44 221 090234 valid until 05 March 2023
acc. to ISO 13485:2016 Certificate 19-1613-M valid through 02 Aug 2023

505 West Ultradent Drive
South Jordan, Utah 84095, USA
www.ultradent.com • 800.552.5512

ULTRADENT PRODUCTS, INC.

DECLARATION OF CONFORMITY

TIPS

Adam Black
Regulatory Affairs Manager

06 July 2022
Date

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

6 **day of** JULY **20** 22

By Adam Black

Amy Henderson-Nielson
Notary Public

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

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