DECLARATION OF CONFORMITY

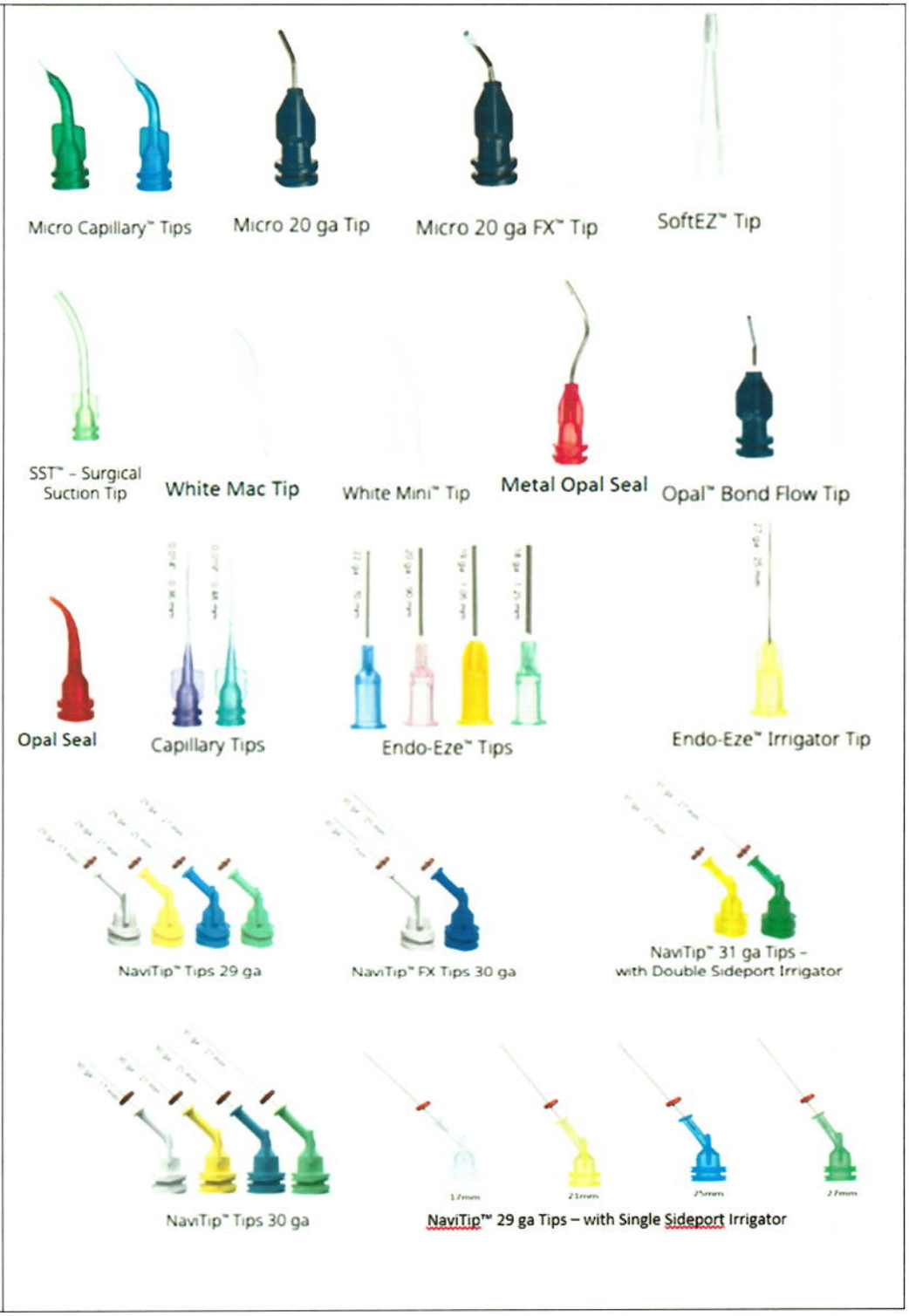
TIPS

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 111, 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 37434, Dental Suction system cannula dental, single use
EMDN 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:	REF/UP: 123,127,128,158,186,190,194,196,207,341,345,346,347,348,514,661 710, 1085, 1086, 1120, 1121, 1168, 1169, 1247, 1248, 1249, 1250,1252, 1296, 1349, 1351,1354, 1356, 1357, 1361,1374, 1376,1377, 1378,1379,1421, 1422, 1423,1424, 1425, 1428, 1429, 1430, 1431, 1432,1433,1434, 1435, 1436, 1437, 1440, 1452, 1454, 1480,1802,2558,2559,2560,3099,3319,4711,4712,4954, 4955,4956,4989,4990,4991,4992,5112,5113,5114,5115,5116,5121,5122, 5123,5124,5143,5922,1033-I,500034,500064,500079,500094,500095,500097
Images:	

DECLARATION OF CONFORMITY

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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:

505 West Ultradent Drive, South Jordan, Utah 84095, USA | 800.552.5512 | ULTRADENT.COM

DECLARATION OF CONFORMITY

TIPS

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

07 September 2023
Date

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

7 **day of** September **20**23

By Adam Black

Amy Henderson-Nielson

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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