

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 37434, Suction system cannula dental, single-use
CND Code:	A0280 – SYRINGES - ACCESSORIES
Basic UDI-DI:	0883205-TF032AQ
Eudamed SRN:	Eudamed is currently unavailable.
Model Numbers:	REF/UP: 122, 123, 125, 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, 1405, 1406, 1421, 1422, 1423, 1424, 1425, 1428, 1429, 1430, 1431, 1432, 1433, 1434, 1435, 1436, 1437, 1440, 1452, 1454, 1480, 1802, 2558, 2559, 2560, 3099, 4711, 4712, 4989, 4990, 4991, 4992, 5112, 5113, 5114, 5115, 5116, 5121, 5122, 5123, 5124, 5143, 5922, 1033-I, 500034, 500064, 500079, 500094, 500095, 500097

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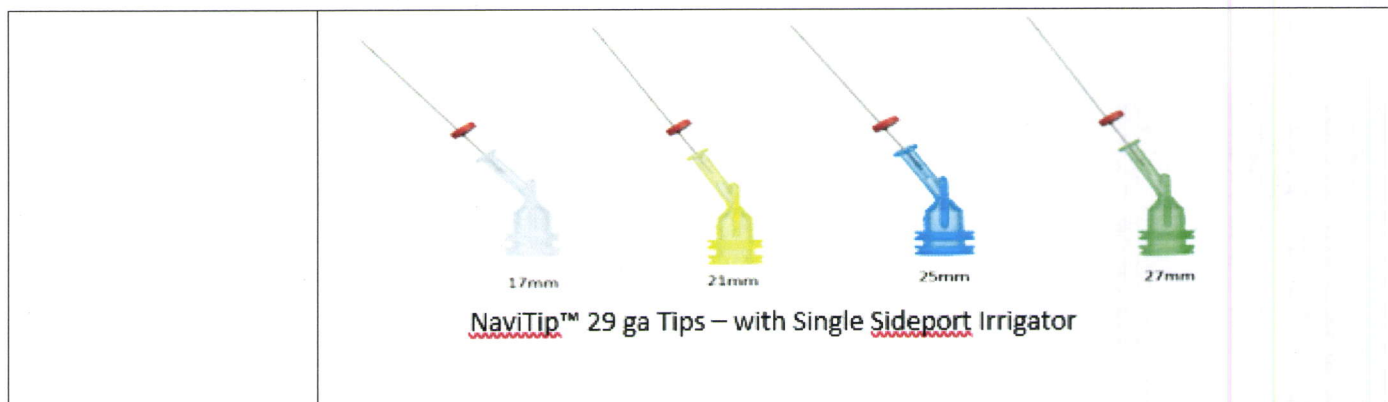
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Images:



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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:

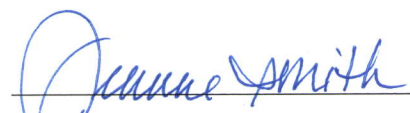
ISO 13485:2016 Certificate 19-1612-Q valid through 02 Aug 2023
 DIN EN ISO 13485:2016 Reg.-No. 44 221 090234 valid until 05 March 2023
 ISO 13485:2016 Certificate 19-1613-M valid through 02 Aug 2023


 Adam Black
 Regulatory Affairs Manager

22 July 2021
 Date

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

22 day of July 20 21
 By Adam Black


 Jeanne Smith, Notary Public

