

# DECLARATION OF CONFORMITY

## UMBRELLA CHEEK RETRACTOR



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.

<b>Identified Legislations:</b>	Regulation (EU) 2017/745 – European Parliament and of the Council of 5 April 2017 on medical devices
<b>EC Representative:</b>	Ultradent Products GmbH Am Westhover Berg 30 51149 Cologne Germany
<b>Device Classification:</b>	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.
<b>Intended Purpose:</b>	Cheek retractor is used for dental procedures maintain the patient's mouth open, cheeks retracted and tongue back and relaxed while providing optimal access to the patient's oral cavity while providing comfort to the patient.
<b>UMDNS Code:</b>	13380, Retractors, Dental
<b>GMDN Code:</b>	63315, Dental cheek retractor, professional, single-use
<b>EMDN Code:</b>	L150201 - DENTAL RETRACTORS
<b>Basic UDI-DI:</b>	0883205-TF319BF
<b>Eudamed SRN:</b>	DE-AR-000006666, DE-IM-000010855, US-MF-000013697
<b>Common Specifications:</b>	Not applicable
<b>Model Numbers:</b>	4870-, 4871-, 5162-, 5256-, 5257-, 5258-
<b>Images:</b>	

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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

  
Adam Black Director - Regulatory Affairs & Clinical Operations

23 Feb 2026  
Date

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

23 day of February 2026  
By Adam Black

  
Notary Public

