



## DECLARATION OF CONFORMITY

Ultradent Products Inc., 505 West Ultradent Drive (10200 South), South Jordan UT, 84095, has evaluated the following product by using the Conformity Assessment Procedure of Annex VII of the Medical Device Directive 93/42/EEC, as amended by 2007/47/EEC:

### Umbrella Cheek Retractor

and confirms that the product is compliant with the Essential Requirements of Annex I of the Medical Device Directive 93/42/EEC. Technical documentation is located in the Regulatory Affairs Department.

This product system is classified as Class I medical device according to the Medical Device Directive 93/42/EEC, Annex IX, Section 2.1 Rule 5 of Section III Classification.

**UMDNS Code:** 13380, Retractors, Dental

**GMDN Code:** 63315, Dental cheek retractor, professional, single-use

**EC Representative:**

Ultradent Products GmbH  
Am Westhover Berg 30  
51149 Cologne  
Germany

Karen Kakunes  
Karen Kakunes  
Director Regulatory Affairs

27 Oct 2020  
Date

State of Utah  
County of Salt Lake

Subscribed and sworn to before me on this 27<sup>th</sup> day of October 2020

By Karen Kakunes

Debbie Anderson  
insert Notaries name, Notary Public



This document is in force as long as the following ISO 13485 certificates are valid:

ISO 13485:2016 Certificate 19-1612-Q valid through 02-Aug-2023 acc. to ISO 13485:2016 Certificate 19-1613-M valid through 02-Aug-2023