

# DECLARATION OF CONFORMITY



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

## UltraEZ

and confirms in sole responsibility 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 IIa medical device according to the Medical Device Directive 93/42/EEC, Annex IX, Section III, Rule 6

**UMDNS Code:** 16183 Cavity Varnish

**GMDN Code:** 64795 Dental coating, tooth-desensitizing, home-use

**EMDN Code:** Q010199 Conservative Dentistry and Endodontic Devices - Other

**EC Representative:**

Ultradent Products GmbH  
Am Westhover Berg 30  
51149 Cologne  
Germany

**Notified Body:**

TÜV Nord Cert GmbH  
Unternehmensgruppe TÜV Nord  
Langemarckstraße 20  
45141 Essen, Germany  
ID No. 0044

  
Adam Black, RAC  
Senior Manager – Regulatory Affairs

22 Feb 2024  
Date

State of Utah  
County of Salt Lake

Subscribed and sworn to before me on this 22 day of February 2024

By Adam Black

  
Notary Public



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

EC Certificate 44 232 090234 with valid extension through 31 December 2028