

## DECLARATION OF CONFORMITY

Ultradent Products, Inc. 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:

### Enamelast

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 Classification 2.1, Rule 5

**UMDNS Code:** 16183, Cavity Varnish

**GMDN Code:** 64794, Dental coating, tooth-desensitizing, professional

**EC Representative:**

Ultradent Products GmbH  
Am Westhoven Berg 30  
51149 Cologne  
Germany

**Notified Body:**

TÜV Nord Cert GmbH  
Unternehmensgruppe TÜV Nord  
Langemarkstraße 20  
45141 Essen, Germany  
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Karen Kakunes RN, BSN

Regulatory Affairs Management

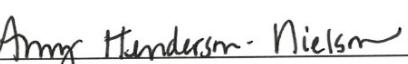
  
02 Dec 2020

Date

State of Utah  
County of Salt Lake

Subscribed and sworn to before me on this 2 day of December 2020

By Karen Kakunes

  
Amy Henderson-Nielsen  
Notary Public

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

EC Certificate 44 232 090234 valid through 26 May 2024