

## 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 II of the Medical Device Directive 93/42/EEC, as amended by 2007/47/EEC:

**Opalescence Boost PF 38%**  
**Opalescence Boost PF 40%**  
**Opalescence Boost 35% non-PF**

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 2.2, Rule 6.

**UMDNS Code:** 17619, Restorative Materials, Dental, Other

**GMDN Code:** 38785, Dental bleaching agent

**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



Karen Kakunes, RN BSN  
Regulatory Affairs Manager

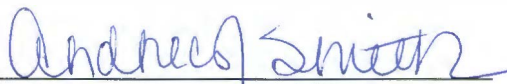


Date

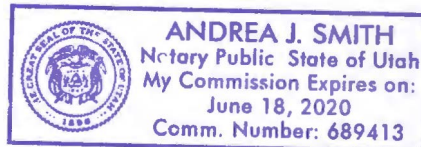
State of Utah  
County of Salt Lake

Subscribed and sworn to before me on this 1<sup>st</sup> day of February 20 18

By Karen Kakunes



Andrea J. Smith, Notary Public



This document is in force as long as the following EC certificates are valid:  
EC Certificate 44 232 090234 valid through 28 January 2021

Class IIa

RP014.09 Released February 1, 2018