ULTRADENT PRODUCTS, INC.

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

01 feb 2018
Date

State of Utah
County of Salt Lake

Subscribed and sworn to before me on this 1st **day of** February **20** 18

By Karen Kakunes

Andrea J. Smith, Notary Public

ANDREA J. SMITH
Notary Public State of Utah
My Commission Expires on:
June 18, 2020
Comm. Number: 689413

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

505 West Ultradent Drive
South Jordan, Utah 84095, USA
www.ultradent.com • 800.552.5512