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:

Opalescence Endo

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 2.3, Rule 7

UMDNS Code: 17619, Restorative Materials, Dental, Other
GMDN Code: 38785, Dental bleaching agent

EC Representative:
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Notified Body:
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ID No. 0044

Karen Kakunes

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 **20**20

By Karen Kakunes

Amy Henderson-Nielson

Notary Public

Amy Henderson-Nielson
NOTARY PUBLIC - STATE OF UTAH
My Comm. Exp. 08/03/2024
Commission # 713340

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

EC Certificate 44 232 090234 valid through 26 May 2024