

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 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

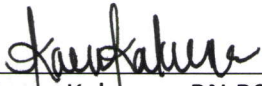
GMDN Code: 38785, Dental bleaching agent

EC Representative:

Ultradent Products GmbH
Am Westhoyer Berg 30
51149 Cologne
Germany

Notified Body:

TÜV Nord Cert GmbH
Unternehmensgruppe TÜV Nord
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ID No. 0044



Karen Kakunes, RN, BSN
Director of Regulatory Affairs

22 Sep 2020

Date

State of Utah
County of Salt Lake

Subscribed and sworn to before me on this 22 day of September 2020

By Karen Kakunes



Amy Henderson-Nielson, 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

Class IIa

RP014.10 Released September 9, 2020