# DECLARATION OF CONFORMITY

Ultradent Products, Inc., 505 W. Ultradent Drive (10200 S.), South Jordan, UT, USA 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 40%

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, Rule 6

**UMDNS Code**: 17619 Restorative Materials, Dental, Other
**GMDN Code**: 38785 Dental bleaching agent
**EMDN Code**: Q010199 Conservative Dentistry and Endodontic Devices - Other

**EC Representative:**
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**Notified Body:**
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Adam Black, RAC
Senior Manager – Regulatory Affairs

22 feb 2024
Date

**State of Utah**
**County of Salt Lake**

**Subscribed and sworn to before me on this** 22 **day of** Febrvary **20** 24

**By** Adam Black

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 with valid extension through 31 December 2028