# 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 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, Classification 2.2, Rule 6.

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

**EC Representative:**
Ultradent Products GmbH
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51149 Cologne
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**Notified Body:**
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ID No. 0044

Karen Kakunes
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 **20**20

**By** Karen Kakunes

Amy Henderson-Nielson
**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