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 Quick PF 45%

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
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