DECLARATION OF CONFORMITY

Ultradent Products, Inc. has evaluated the following product by using the Conformity Assessment Procedure of Annex VII of the Medical Device Directive 93/42/EEC, as amended by 2007/47/EEC:

Opalustre

and confirms 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 I medical device according to the Medical Device Directive 93/42/EEC, Annex IX, Section III Classification, 2.1 Rule 5

UMDNS Code: 16699, Prophy Pastes
GMDN Code: 11168, Dentifrice

EC Representative:
Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne
Germany

Adam Black
Regulatory Affairs Manager

23 Nov 2020
Date

State of Utah
County of Salt Lake

Subscribed and sworn to before me on this 23 **day of** November **20** 20

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 ISO 13485 certificates are valid:

ISO 13485:2016 Certificate 19-1612-Q valid through 02-Aug-2023
acc. to ISO 13485:2016 Certificate 19-1613-M valid through 02-Aug-2023