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:

UltraSeal XT hydro

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 5

UMDNS Code: 16736 Composite Restorative Material Kits, Dental, Light-Cured
GMDN Code: 34771 Dental unfilled resin sealant/coating
EMDN Code: Q010199 Conservative Dentistry and Endodontic Devices - Other

EC Representative:
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Notified Body:
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Langemarckstraße 20
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ID No. 0044

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** February **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