DECLARATION OF CONFORMITY

Ultradent Products, Inc. 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:

Ultra-Blend plus

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 2.4, Rule 8

UMDNS Code: 16182, Cavity Liner
GMDN Code: 47232, Calcium hydroxide dental suspension

EC Representative:
Ultradent Products GmbH
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51149 Cologne
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Notified Body:
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Unternehmensgruppe TüV Nord
Langemarckstraβe 20
45141 Essen, Germany
ID No. 0044

Karen Kakunes

Karen Kakunes RN, BSN
Regulatory Affairs Management

02 Dec 2020
Date

State of Utah
County of Salt Lake

Subscribed and sworn to before me on this 2 **day of** December **20**20

By Karen Kakunes

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

Digitally signed by Bolgari Irina
Date: 2022.05.24 14:27:34 EEST
Reason: MoldSign Signature
Location: Moldova

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