

## **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:

## **UltraCal XS, Calcium Hydroxide Paste**

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. 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 **Notified Body: EC Representative:** TÜV Nord Cert GmbH Ultradent Products GmbH Unternehmensgruppe TüV Nord Am Westhover Berg 30 Langemarckstraße 20 51149 Cologne 45141 Essen, Germany Germany ID No. 0044 Regulatory Affairs Management State of Utah County of Salt Lake Subscribed and sworn to before me on this 2 day of December By Karen Kakines

Anny Henderen - Dulin

Notary Public

This document is in force as long as the following EC certificates are valid:

EC Certificate 44 232 090234 valid through 26 May 2024

Amy Henderson-Nielson NOTARY PUBLIC - STATE OF UTAH My Comm. Exp. 08/03/2024 Commission # 713340