

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. 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

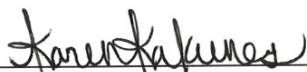
GMDN Code: 47232, Calcium hydroxide dental suspension

EC Representative:

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Notified Body:

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Karen Kakunes RN, BSN
Regulatory Affairs Management




Date

State of Utah
County of Salt Lake

Subscribed and sworn to before me on this 2 day of December 2020

By Karen Kakunes


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