Ozdent
Dental Products Australia

EC DECLARATION OF CONFORMITY

Manufacturer:	**Ozdent Pty Ltd** 12/6 Gladstone Rd, Castle Hill, 2154, NSW, Australia
European Representative	**Annette Callaghan Ireland Limited** Lee View House, South Terrace, Cork, Ireland

Product:	Calmix, Dental Cavity Liner
Classification:	IIa, Rule 8
Conformity Assessment Route:	Medical Devices Directive 93/42/EEC, Annex II (excluding section 4)
Batch No.	072021-5
Date of Manufacture	16-07-2020
Expiry Date	07-2023

We hereby declare, exclusively, under sole responsibility, that the above mentioned product/s meet the provisions of the council directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:	BS EN ISO 13485	BS EN 1641	MEDDEV 2.7.1	EN 1041
	BS EN ISO 14971	EN ISO 15223	BS EN ISO 10993-1	BS EN ISO 10993-5
	BS EN ISO 10993-1	BS EN ISO 10993-5	BS EN 62366	
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany Notified Body No.: 0123			
(EC) Certificate(s) No.:	G1 096382 0006 Rev.00			
Start of CE-Marking:	December 15, 2017			

Signed for on behalf of Ozdent Pty Ltd (Australia) who are responsible for the issuance, maintenance, extension, suspension or withdrawal of this Declaration of Conformity.

Joshua Tadros
Director (NSW, Australia)

Date: 10/09/2020