Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
AdDent, Inc.	43 Miry Brook Road Danbury, CT 06810 USA	US-MF-000019453

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Phone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	**Code / Catalog Number**
Calset Composite Warmer & Trays	110000
Voco Caps Warmer (Voco Ref 9001) Voco Caps Warmer – Caps Tray (Voco Ref 9003)	110008-70
Intended Purpose	**Basic UDI-DI**
The Calset and Caps Warmer units are used to warm dental composite materials to 130˚F (54˚C) or 155˚F (68˚C). It is also used to warm anesthetic carpules to 98˚F (37˚C) (body temperature).	+D8691100000

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	I	ISO 9001:2015 certified, ISO 13485:2016 compliant, FDA 510(k) K061395, FDA - Good Manufacturing Practices (GMPs), ISO 14971:2012, ANSI/AAMI/IEC 60601-1, EMC ANSI/AAMI/IEC 60601-1-2
Rule:	13	

AdDent, Inc. declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745
- RoHs (EU) 2015/863

COMPANY REPRESENTATIVE: Dr. Joshua Friedman

TITLE: President

SIGNATURE:



PLACE: Danbury, CT USA

DATE: 08/1/2022