EC Declaration of Conformity

We declare, under our sole responsibility, that the products listed below are in conformity with The European Council Directive; Medical Device Directive (MDD) 93/42/EEC of 14 June 1993 as amended to 2007/47/EC and the Essential Requirements as described in Annex I of the Directive are fulfilled.					
Manufacturer's Name and Business Address:	DENTCA, Inc. 357 Van Ness Way, Suite 250 Torrance, CA 90501, USA				
EC REP	MT Promedt Consulting GmbH Altenhofstrasse 80 66386 St Ingbert. Germany				
Product Group	**Denture Base II**				
Product Type	**Dental appliance fabrication material, cured**				
UMDNS terms	Denture Base Resins		UMDNS code	16728	
Medical Device Conformity Assessment Route Annex:	II excluding section 4				
Medical Device Classification	IIa		Medical Device Classification Rules:	5	
Notified Body	TÜV NORD CERT GmbH (CE0044)				
Certificate Number	44 232 181 718	Valid from	2020-11-23	Valid till	2024-03-28

Standards Applied	
ISO 20795-1:2013	Dentistry-Base Polymers – Part1: Denture base polymers
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical devices
EN ISO 15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied.
EN ISO 1041:2008	Information Supplied by the Manufacturer of Medical devices
ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
ISO 10993-17:2002	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2005	Biological evaluation of medical devices – Part 18: Chemical characterization of materials
EN 62366:2008	Medical Devices - Application of Usability Engineering to Medical devices

Product List

Product Name	**Shade (Variations)**	**Reference #**	**UDI-DI**
dima Print Denture Base	Light Pink	66081671	J014660816710
	Original Pink	66081672	J014660816720
	Reddish Pink	66081670	J014660816700
	Dark Pink	66081673	J014660816730
dima Print Denture Base Try-in	White	66081666	J014660816660
	Pink	66081669	J014660816690

Authorized Signatory:

Quality Management Representative: **Jason Lee**

Date: 2021-12-07