

DECLARATION OF CONFORMITY

We, Dentonics, Inc.
2833, Tophill Road
Monroe, NC 28110
USA

Declare on our own responsibility that the following Medical Devices:

Meet all the provisions of the directive: 93/42/EEC (Amended in 2007) Annex II which apply to it.

Applied Norms: ISO 9001, ISO 13485, ISO 14971

Related guidance documents: MEDDEV 2.12.-1 Rev. 6
MEDDEV 2.5/9 Rev. 1

Other Normative Documents: CE Mark (Annex V) Certificate No. EU1108408

Notified Body: IQNet and Nemko AS
ISO 9001:2008 Certificate No. 800535
ISO 13485:2003 Certificate No: 908184

All Items are: Class IIa: According to Annex IX of guideline 93/42/CEE

<u>PRODUCT DESCRIPTION</u>	<u>PRODUCT FAMILY</u>	<u>RULE #</u>	<u>UMDNS</u>
Pit & Fissure Sealant Light Cure Syringes Kit	Preventives	5	31780
Pit & Fissure Sealant Light Cure Bottle Kit	Preventives	5	31780
Pit & Fissure Sealant Chemical Cure Kit	Preventives	5	31780
Etching Gel	Etching Agents	6	36153
Temporary Crown & Bridge Material	Acrylics	7	31783
Temporary Filling Material Light Cure	Endodontic	7	16704
Temporary Filling Material in jar	Endodontic	7	35870
Zinc Oxide Powder	Endodontic	8	16709
USP grade Eugenol	Endodontic	8	16709
Root Canal Sealer Cement Kit	Endodontic	8	36095
Dentin/Enamel Bond Light Cure	Bonding Agents	8	42483
Self Etching Bond Light Cure	Bonding Agents	8	42483
Calcium Hydroxide Cavity Liner Light Cure	Cements & Liners	8	16182
Temporary Cement Non-Eugenol	Cements & Liners	8	16703
Glass Ionomer Cement (Luting)	Cements & Liners	8	16704

<u>PRODUCT DESCRIPTION</u>	<u>PRODUCT FAMILY</u>	<u>RULE #</u>	<u>UMDNS</u>
Glass Ionomer Water Mixable Cement	Cements & Liners	8	16704
Glass Ionomer Liner	Cements & Liners	8	16704
Glass Ionomer One Component Light Cure Cement	Cements & Liners	8	16704
Polycarboxylate Cement	Cements & Liners	8	16705
Zinc Oxide Eugenol Cement Kit	Cements & Liners	8	16709
Reinforced ZOE Cement Kit	Cements & Liners	8	16709
ZOE Reinforced Cement (IRM Type)	Cements & Liners	8	16709
Zinc Phosphate Cement	Cements & Liners	8	16710
Copal Dental Cavity Varnish	Cements & Liners	8	35698
Copal Dental Cavity Varnish kit	Cements & Liners	8	35698
Resin Cement Chemical Cure	Cements & Liners	8	35870
Resin Cement Plus Chemical Cure	Cements & Liners	8	35870
Glass Ionomer Filling Cement	Composites & Restoratives	8	16704
Chemical Cure Composite	Composites & Restoratives	8	35875
Chemical Cure Composite with etching/bonding	Composites & Restoratives	8	35875
Light Cure Hybrid Composite Kit	Composites & Restoratives	8	35875
Light Cure Hybrid Composite Syringe	Composites & Restoratives	8	35875
Light Cure Hybrid Composite Compules	Composites & Restoratives	8	35875
Light Cure Microhybrid Composite Kit	Composites & Restoratives	8	35875
Light Cure Microhybrid Composite Syringe	Composites & Restoratives	8	35875
Light Cure Microhybrid Composite Compules	Composites & Restoratives	8	35875
Light Cure Flowable Composite Kit	Composites & Restoratives	8	35875
Light Cure Flowable Composite Syringe	Composites & Restoratives	8	35875
Core Build-up Material Light Cure	Core Build-up	8	38789
Orthodontic Bracket Adhesive Chemical Cure	Orthodontic	8	31750

Yours faithfully,

RANDY LEANDER
PRESIDENT

March 29, 2012

DATE

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COMPANY STAMP