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Tel: (773) 283-2914 Fax: (773) 283-3085
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www.primedentalmfg.com

An ISO 13485:2003, ISO 9001:2008 & CE Marked Products Company

DECLARATION OF CONFIRMITY EC Directive

February 14, 2017

We, Prime Dental Manufacturing, Inc., hereby declare that the product listed below, to which this Declaration of Conformity relates, is in conformity with Directives, Standards and other Normative Documents as listed.

- Annex II, excluding section 4, of Council Directive 93/42/EEC as amended by Directive 2007/47/EC.
- ISO 9001:2008 Quality Management Systems Requirements
- ISO 13485:2003 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- FDA registered manufacturer of Dental Products. (FDA registration No. 1424442)
- European Notifying Body: SGS (CE0120)

Type of Product: Dental Polymer Based Filling and Restorative Materials **Technical File No.: TF01**

Class: IIa

Product Names: Prime-Dent Light Cure Hybrid Composite
Prime-Dent Light Cure Micro-Hybrid Composite
Prime-Dent Light Cure Nano-Hybrid Composite
Prime-Dent Light Cure Posterior Composite
Prime-Dent Light Cure Anterior Composite
Prime-Dent Light Cure Flowable Composite
Prime-Dent Light Cure Surface Sealant
Prime-Dent Esthetic Kit
Prime-Dent Chemical Cure Composite
Parafil
Parafil LAB
Parafil Gingiva
Parafil Stains

Type of Product: Dental Bonding Agents **Technical File No.: TF02**

Class: IIa

Product Names: Prime-Dent Light Cure One-Step Dentin/Enamel Bonding Adhesive
Prime-Dent Light Cure Dentin/Enamel Bonding Adhesive
Prime-Dent Chemical Cure Dentin/Enamel Bonding Adhesive
Prime-Dent Light Cure Self-Etch Prime & Bond
Parafil Primer

Type of Product: Dental Cements **Technical File No.: TF03**

Class: IIa

Product Names: Prime-Dent Glass Ionomer Powder/Liquid Cement
Prime-Dent Glass Ionomer Restorative Cement
Prime-Dent Visible Light Cure Glass Ionomer Restorative
Prime-Dent Zinc Oxide Cement
Prime-Dent Zinc Phosphate Cement
Prime-Dent Polycarboxylate Cement

Type of Product: Dental Polymer Based Luting Cements

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Technical File No.: TF04

Class: IIa
Product Names: Prime-Dent Luting Cement
Prime-Dent Dual Cure Composite Luting Cement
Prime-Dent Automix Dual Cure Composite Luting Cement

Type of Product: Dental Core Build Up Materials

Technical File No.: TF05

Class: IIa
Product Names: Prime-Dent Chemical Cure Core Build-Up Material
Prime-Dent Light Cure Core Build-Up Material
Prime-Dent Automix Dual Cure Core Build-Up Material

Type of Product: Dental Root Canal Filling Materials

Technical File No.: TF06

Class: IIa
Product Names: Prime-Dent Root Canal Filling Material

Type of Product: Dental Temporary Cements

Technical File No.: TF07

Class: IIa
Product Names: Prime-Dent Resin Based Non-Eugenol Temporary Cement
Prime-Dent Automix Dual Cure Temporary Cement
Prime-Dent Temporary Cement
Prime-Dent Surgical Cement

Type of Product: Dental Etching Materials

Technical File No.: TF08

Class: IIa
Product Names: Prime-Dent Etchant Gel
Prime-Dent Etchant Gel Silica Free
Prime-Dent Etchant Liquid
Prime-Dent Etchant Liquid Silica Free
Prime-Dent Porcelain Etchant Gel
Prime-Dent Para-Sil

Type of Product: Orthodontic Adhesives

Technical File No.: TF09

Class: IIa
Product Names: Prime-Dent Paste/Paste Orthodontic Adhesive
Prime-Dent One-Step Orthodontic Adhesive
Prime-Dent Visible Light Cure Orthodontic Adhesive
Prime-Dent Megaset
Prime-Dent Dual Cure Glass Ionomer Band Cement

Type of Product: Dental Pit and Fissure Sealants

Technical File No.: TF10

Class: IIa
Product Names: Prime-Dent Light Cure Pit and Fissure Sealant
Prime-Dent Chemical Cure Pit and Fissure Sealant

Type of Product: Dental Desensitizer

Technical File No.: TF11

Class: IIa



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Product Names: Prime-Dent Hema Desensitizer

Type of Product: Dental Root Canal Cleaning and Lubricating Gel

Technical File No.: TF12

Class: IIa

Product Names: RC-Cream

Type of Product: Dental Temporary Crown and Bridge Materials

Technical File No.: TF13

Class: IIa

Product Names: Prime-Crown

Type of Product: Bracket Bond Enhancers

Technical File No.: TF14

Class: IIa

Product Names: Prime-Dent Metal Bond Enhancer

Prime-Dent Plastic Bond Enhancer

Prime-Dent Porcelain Bond Enhancer

Name of European Representative

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Javier Alvarez
Quality Assurance

