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An ISO 13485:2016, & CE Marked Products Company

DECLARATION OF CONFIRMITY EC Directive

January 13, 2020

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 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- FDA registered manufacturer of Dental Products. (FDA registration No. 1424442)
- European Notifying Body: SGS Belgium NV (CE1639)

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

Class: IIa, Rule 8

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 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, Rule 8

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

Prime-Dent Surface Sealant

Parafil Primer

Type of Product: Dental Cements

Technical File No.: TF03

Class: IIa, Rule 8

Product Names: Prime-Dent Glass Ionomer Powder/Liquid Cement

Prime-Dent Glass Ionomer Restorative Cement

Prime-Dent Light Cured Glass Ionomer Restorative

Prime-Dent Zinc Oxide Cement



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Prime-Dent Zinc Phosphate Cement
Prime-Dent Polycarboxylate Cement

Type of Product: Dental Polymer Based Luting Cements

Technical File No.: TF04

Class: IIa, Rule 8

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, Rule 8

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, Rule 8

Product Names: Prime-Dent Root Canal Filling Material

Type of Product: Dental Temporary Cements

Technical File No.: TF07

Class: IIa, Rule 5

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
Prime-Dent Dental Dam Material

Type of Product: Dental Etching Materials

Technical File No.: TF08

Class: IIa, Rule 6

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 Porcelain Repair Kit
Prime-Dent Citrus Acid

Type of Product: Orthodontic Adhesives

Technical File No.: TF09

Class: IIa, Rule 8

Product Names: Prime-Dent Paste/Paste Orthodontic Adhesive
Prime-Dent One-Step Orthodontic Adhesive
Prime-Dent Visible Light Cure Orthodontic Adhesive
Prime-Dent Megaset



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Prime-Dent Dual Cure Glass Ionomer Band Cement

Type of Product: Dental Pit and Fissure Sealants and Liners
Technical File No.: TF10

Class: IIa, Rule 8
Product Names: Prime-Dent Light Cure Pit and Fissure Sealant
Prime-Dent Chemical Cure Pit and Fissure Sealant
Prime-Blend Ultra
Prime-Dent Copal Varnish

Type of Product: Dental Desensitizer
Technical File No.: TF11

Class: IIa, Rule 6
Product Names: Prime-Dent Hema Desensitizer

Type of Product: Dental Root Canal Cleaning and Lubricating Gel
Technical File No.: TF12

Class: IIa, Rule 6
Product Names: RC-Cream
Prime-Gel

Type of Product: Dental Temporary Crown and Bridge Materials
Technical File No.: TF13

Class: IIa, Rule 5
Product Names: Prime-Crown

Type of Product: Bracket Bond Enhancers
Technical File No.: TF14

Class: IIa, Rule 6
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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Quality Assurance

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