



4555 West Addison Street – Chicago, Illinois 60641  
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An ISO 13485:2016, & CE Marked Products Company

**DECLARATION OF CONFIRMITY**  
 EC Directive

January 4, 2024

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.
- Technical Regulations on Medical Products to Approved by order of the cabinet of Ministers of Ukraine dated 2.10.2013 #753 Rev 8.
- 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)

**Actor Number / SRN:**  
**Manufacturer:**

Manufacturer US-MF-000008807  
 Prime Dental Manufacturing, Inc.  
 4555 W Addison St  
 Chicago, Illinois 60641 USA

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

Class: IIa, Rule 8

Product Names:

- Prime-Dent Light Cure Micro-Hybrid Composite
- Prime-Dent Light Cure Hybrid Composite
- Prime-Dent Light Cure Nano-Hybrid Composite
- Prime-Dent Light Cure Flowable Composite
- Prime-Dent Esthetic Kit
- Parafil
- Parafil LAB
- Parafil Gingiva
- Parafil Stains
- Prime-Dent Chemical Cure Composite

ITEM NUMBER	DESCRIPTION	UDI
	<b>Prime-Dent Light Cure Micro-Hybrid Composite</b>	
001-410	VLC Micro-Hybrid Composite 7 Syringe Kit	00817441020982
001-414	VLC Micro-Hybrid Composite 4 Syringe Kit	00817441020999
001-416	VLC Micro-Hybrid Composite 2 Syringe Kit	00817441021002
001-401A1	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [A1]	00817441020968
001-401A2	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [A2]	00817441020975
001-401A3	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [A3]	00817441020784
001-401A3.5	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [A3.5]	00817441020791
001-401A4	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [A4]	00817441020807
001-401B1	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [B1]	00817441020814
001-401B2	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [B2]	00817441020821



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001-401B3	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [B3]	00817441020838
001-401B4	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [B4]	00817441020845
001-401C1	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [C1]	00817441020852
001-401C2	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [C2]	00817441020869
001-401C3	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [C3]	00817441020876
001-401C4	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [C4]	00817441020883
001-401D2	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [D2]	00817441020890
001-401D3	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [D3]	00817441020906
001-401D4	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [D4]	00817441020913
001-401I	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [Incisal]	00817441023877
001-401O	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [Opaque]	00817441023884
001-401OA2	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [OA2] (DENTIN)	00817441020920
001-401OA3	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [OA3] (DENTIN)	00817441020937
001-401OA3.5	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [OA3.5] (DENTIN)	00817441020944
001-401OA4	VLC Micro-Hybrid Composite 4.5 g Syringe Refill [OA4] (DENTIN)	00817441020951
001-419A1	VLC Micro-Hybrid Composite 20 Compules x .20 g each [A1]	00817441023891
001-419A2	VLC Micro-Hybrid Composite 20 Compules x .20 g each [A2]	00817441023907
001-419A3	VLC Micro-Hybrid Composite 20 Compules x .20 g each [A3]	00817441023914
001-419A3.5	VLC Micro-Hybrid Composite 20 Compules x .20 g each [A3.5]	00817441023921
001-419A4	VLC Micro-Hybrid Composite 20 Compules x .20 g each [A4]	00817441023938
001-419B1	VLC Micro-Hybrid Composite 20 Compules x .20 g each [B1]	00817441023945
001-419B2	VLC Micro-Hybrid Composite 20 Compules x .20 g each [B2]	00817441023952
001-419B3	VLC Micro-Hybrid Composite 20 Compules x .20 g each [B3]	00817441023969
001-419B4	VLC Micro-Hybrid Composite 20 Compules x .20 g each [B4]	00817441023976
001-419C1	VLC Micro-Hybrid Composite 20 Compules x .20 g each [C1]	00817441023983
001-419C2	VLC Micro-Hybrid Composite 20 Compules x .20 g each [C2]	00817441023990
001-419C3	VLC Micro-Hybrid Composite 20 Compules x .20 g each [C3]	00817441024003
001-419C4	VLC Micro-Hybrid Composite 20 Compules x .20 g each [C4]	00817441024010
001-419D2	VLC Micro-Hybrid Composite 20 Compules x .20 g each [D2]	00817441024027
001-419D3	VLC Micro-Hybrid Composite 20 Compules x .20 g each [D3]	00817441024034
001-419D4	VLC Micro-Hybrid Composite 20 Compules x .20 g each [D4]	00817441024041
001-419I	VLC Micro-Hybrid Composite 20 Compules x .20 g each [Incisal]	00817441024058
001-419O	VLC Micro-Hybrid Composite 20 Compules x .20 g each [Opaque]	00817441024065
001-419OA2	VLC Micro-Hybrid Composite 20 Compules x .20 g each [OA2] (DENTIN)	00817441024072
001-419OA3	VLC Micro-Hybrid Composite 20 Compules x .20 g each [OA3] (DENTIN)	00817441024089
001-419OA3.5	VLC Micro-Hybrid Composite 20 Compules x .20 g each [OA3.5] (DENTIN)	00817441024096
001-419OA4	VLC Micro-Hybrid Composite 20 Compules x .20 g each [OA4] (DENTIN)	00817441024102
	<b>Prime-Dent Light Cure Hybrid Composite</b>	
001-010	VLC Hybrid Composite 7 Syringe Kit	00817441020753
001-009	VLC Hybrid Composite 7 Syringe Kit [with Etch Gel in Syringe	00817441020753
001-014	VLC Hybrid Composite 4 Syringe Kit	00817441020760
001-016	VLC Hybrid Composite 2 Syringe Kit	00817441020777
001-001A1	VLC Hybrid Composite 4.5 g Syringe Refill [A1]	00817441020517
001-001A2	VLC Hybrid Composite 4.5 g Syringe Refill [A2]	00817441020524
001-001A3	VLC Hybrid Composite 4.5 g Syringe Refill [A3]	00817441020326
001-001A3.5	VLC Hybrid Composite 4.5 g Syringe Refill [A3.5]	00817441020333
001-001A4	VLC Hybrid Composite 4.5 g Syringe Refill [A4]	00817441020340
001-001B1	VLC Hybrid Composite 4.5 g Syringe Refill [B1]	00817441020357
001-001B2	VLC Hybrid Composite 4.5 g Syringe Refill [B2]	00817441020364
001-001B3	VLC Hybrid Composite 4.5 g Syringe Refill [B3]	00817441020371
001-001B4	VLC Hybrid Composite 4.5 g Syringe Refill [B4]	00817441020388
001-001C1	VLC Hybrid Composite 4.5 g Syringe Refill [C1]	00817441020395
001-001C2	VLC Hybrid Composite 4.5 g Syringe Refill [C2]	00817441020401
001-001C3	VLC Hybrid Composite 4.5 g Syringe Refill [C3]	00817441020418
001-001C4	VLC Hybrid Composite 4.5 g Syringe Refill [C4]	00817441020425



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001-001D2	VLC Hybrid Composite 4.5 g Syringe Refill [D2]	00817441020432
001-001D3	VLC Hybrid Composite 4.5 g Syringe Refill [D3]	00817441020449
001-001D4	VLC Hybrid Composite 4.5 g Syringe Refill [D4]	00817441020456
001-001I	VLC Hybrid Composite 4.5 g Syringe Refill [Incisal]	00817441020463
001-001O	VLC Hybrid Composite 4.5 g Syringe Refill [Opaque]	00817441020470
001-001OA2	VLC Hybrid Composite 4.5 g Syringe Refill [OA2] (DENTIN)	00817441020487
001-001OA3	VLC Hybrid Composite 4.5 g Syringe Refill [OA3] (DENTIN)	00817441020494
001-001OA3.5	VLC Hybrid Composite 4.5 g Syringe Refill [OA3.5] (DENTIN)	00817441020500
001-019A1	VLC Hybrid Composite 20 Compules x .20 g each [A1]	00817441024119
001-019A2	VLC Hybrid Composite 20 Compules x .20 g each [A2]	00817441024126
001-019A3	VLC Hybrid Composite 20 Compules x .20 g each [A3]	00817441024133
001-019A3.5	VLC Hybrid Composite 20 Compules x .20 g each [A3.5]	00817441024140
001-019A4	VLC Hybrid Composite 20 Compules x .20 g each [A4]	00817441024157
001-019B1	VLC Hybrid Composite 20 Compules x .20 g each [B1]	00817441024164
001-019B2	VLC Hybrid Composite 20 Compules x .20 g each [B2]	00817441024171
001-019B3	VLC Hybrid Composite 20 Compules x .20 g each [B3]	00817441024188
001-019B4	VLC Hybrid Composite 20 Compules x .20 g each [B4]	00817441024195
001-019C1	VLC Hybrid Composite 20 Compules x .20 g each [C1]	00817441024201
001-019C2	VLC Hybrid Composite 20 Compules x .20 g each [C2]	00817441024218
001-019C3	VLC Hybrid Composite 20 Compules x .20 g each [C3]	00817441024225
001-019C4	VLC Hybrid Composite 20 Compules x .20 g each [C4]	00817441024232
001-019D2	VLC Hybrid Composite 20 Compules x .20 g each [D2]	00817441024249
001-019D3	VLC Hybrid Composite 20 Compules x .20 g each [D3]	00817441024256
001-019D4	VLC Hybrid Composite 20 Compules x .20 g each [D4]	00817441024263
001-019I	VLC Hybrid Composite 20 Compules x .20 g each [Incisal]	00817441024270
001-019O	VLC Hybrid Composite 20 Compules x .20 g each [Opaque]	00817441024287
001-019OA2	VLC Hybrid Composite 20 Compules x .20 g each [OA2] (DENTIN)	00817441024294
001-019OA3	VLC Hybrid Composite 20 Compules x .20 g each [OA3] (DENTIN)	00817441024300
001-019OA3.5	VLC Hybrid Composite 20 Compules x .20 g each [OA3.5] (DENTIN)	00817441024317
	<b>Prime-Dent Light Cure Nano-Hybrid Composite</b>	
001-610	VLC Nano-Hybrid Composite 7 Syringe Kit	00817441020005
001-614	VLC Nano-Hybrid Composite 4 Syringe Kit	00817441024324
001-616	VLC Nano-Hybrid Composite 2 Syringe Kit	00817441024331
001-601A1	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [A1]	00817441020012
001-601A2	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [A2]	00817441020029
001-601A3	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [A3]	00817441020036
001-601A3.5	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [A3.5]	00817441020043
001-601A4	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [A4]	00817441020050
001-601B1	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [B1]	00817441020067
001-601B2	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [B2]	00817441020074
001-601B3	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [B3]	00817441020081
001-601B4	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [B4]	00817441020098
001-601C1	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [C1]	00817441020104
001-601C2	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [C2]	00817441020111
001-601C3	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [C3]	00817441020128
001-601C4	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [C4]	00817441020135
001-601D2	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [D2]	00817441020142
001-601D3	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [D3]	00817441020159
001-601D4	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [D4]	00817441020166
001-601I	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [Incisal]	00817441024348
001-601O	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [Opaque]	00817441024355
001-601OA2	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [OA2] (DENTIN)	00817441020173
001-601OA3	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [OA3] (DENTIN)	00817441020180
001-601OA3.5	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [OA3.5] (DENTIN)	00817441020197
001-601OA4	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [OA4]	00817441020203
001-601UO	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [Universal Opaque]	00817441020210



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001-601UD	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [Universal Dentin]	00817441020227
001-601DT	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [Dark Translucent]	00817441020234
001-601CT	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [Clear Translucent]	00817441020241
001-601NT	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [Natural Translucent]	00817441020258
001-601ET4	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [ET4]	00817441020265
001-601B	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [Incisal Blue]	00817441020272
001-601U	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [Incisal Universal]	00817441020289
001-601Y	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [Incisal Yellow]	00817441020296
001-601OTB	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [OTB]	00817441020302
001-601OTG	VLC Nano-Hybrid Composite 4.5 g Syringe Refill [OTG]	00817441020319
001-619A1	VLC Nano-Hybrid Composite 20 Compules x .20 g each [A1]	00817441024362
001-619A2	VLC Nano-Hybrid Composite 20 Compules x .20 g each [A2]	00817441024379
001-619A3	VLC Nano-Hybrid Composite 20 Compules x .20 g each [A3]	00817441024386
001-619A3.5	VLC Nano-Hybrid Composite 20 Compules x .20 g each [A3.5]	00817441024393
001-619A4	VLC Nano-Hybrid Composite 20 Compules x .20 g each [A4]	00817441024409
001-619B1	VLC Nano-Hybrid Composite 20 Compules x .20 g each [B1]	00817441024416
001-619B2	VLC Nano-Hybrid Composite 20 Compules x .20 g each [B2]	00817441024423
001-619B3	VLC Nano-Hybrid Composite 20 Compules x .20 g each [B3]	00817441024430
001-619B4	VLC Nano-Hybrid Composite 20 Compules x .20 g each [B4]	00817441024447
001-619C1	VLC Nano-Hybrid Composite 20 Compules x .20 g each [C1]	00817441024454
001-619C2	VLC Nano-Hybrid Composite 20 Compules x .20 g each [C2]	00817441024461
001-619C3	VLC Nano-Hybrid Composite 20 Compules x .20 g each [C3]	00817441024478
001-619C4	VLC Nano-Hybrid Composite 20 Compules x .20 g each [C4]	00817441024485
001-619D2	VLC Nano-Hybrid Composite 20 Compules x .20 g each [D2]	00817441024492
001-619D3	VLC Nano-Hybrid Composite 20 Compules x .20 g each [D3]	00817441024508
001-619D4	VLC Nano-Hybrid Composite 20 Compules x .20 g each [D4]	00817441024515
001-619I	VLC Nano-Hybrid Composite 20 Compules x .20 g each [Incisal]	00817441024522
001-619O	VLC Nano-Hybrid Composite 20 Compules x .20 g each [Opaque]	00817441024539
001-619OA2	VLC Nano-Hybrid Composite 20 Compules x .20 g each [OA2] (DENTIN)	00817441024546
001-619OA3	VLC Nano-Hybrid Composite 20 Compules x .20 g each [OA3] (DENTIN)	00817441024553
001-619OA3.5	VLC Nano-Hybrid Composite 20 Compules x .20 g each [OA3.5] (DENTIN)	00817441024560
001-619OA4	VLC Nano-Hybrid Composite 20 Compules x .20 g each [OA4]	00817441024577
001-619UO	VLC Nano-Hybrid Composite 20 Compules x .20 g each [Universal Opaque]	00817441024584
001-619UD	VLC Nano-Hybrid Composite 20 Compules x .20 g each [Universal Dentin]	00817441024591
001-619DT	VLC Nano-Hybrid Composite 20 Compules x .20 g each [Dark Translucent]	00817441024607
001-619CT	VLC Nano-Hybrid Composite 20 Compules x .20 g each [Clear Translucent]	00817441024614
001-619NT	VLC Nano-Hybrid Composite 20 Compules x .20 g each [Natural Translucent]	00817441024621
001-619ET4	VLC Nano-Hybrid Composite 20 Compules x .20 g each [ET4]	00817441024638
001-619B	VLC Nano-Hybrid Composite 20 Compules x .20 g each [Incisal Blue]	00817441024645
001-619U	VLC Nano-Hybrid Composite 20 Compules x .20 g each [Incisal Universal]	00817441024652
001-619Y	VLC Nano-Hybrid Composite 20 Compules x .20 g each [Incisal Yellow]	00817441024669
001-619OTB	VLC Nano-Hybrid Composite 20 Compules x .20 g each [OTB]	00817441024676
001-619OTG	VLC Nano-Hybrid Composite 20 Compules x .20 g each [OTG]	00817441024683
	<b>Prime-Dent Light Cure Flowable Composite</b>	
004-010	VLC Flowable Composite Kit (4-2 g Syringes) 4 Shades (A2,A3,A3.5,B2)	00817441020746
004-010A1	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (A1)	00817441024690
004-010A2	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (A2)	00817441024706
004-010A3	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (A3)	00817441024713
004-010A3.5	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (A3.5)	00817441024720
004-010A4	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (A4)	00817441024737
004-010B1	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (B1)	00817441024744
004-010B2	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (B2)	00817441024751
004-010B3	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (B3)	00817441024768
004-010B4	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (B4)	00817441024775





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004-010C1	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (C1)	00817441024782
004-010C2	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (C2)	00817441024799
004-010C3	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (C3)	00817441024805
004-010C4	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (C4)	00817441024812
004-010D2	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (D2)	00817441024829
004-010D3	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (D3)	00817441024836
004-010D4	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (D4)	00817441024843
004-010I	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (Incisal)	00817441024850
004-010O	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (Opaque)	00817441024867
004-010OA2	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (OA2)	00817441024874
004-010OA3	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (OA3)	00817441024881
004-010OA3.5	VLC Flowable Composite Kit (4-2 g Syringes) 1 Shade (OA3.5)	00817441024898
004-101A1	VLC Flowable Composite 2 g Syringe Refill [A1]	00817441020722
004-101A2	VLC Flowable Composite 2 g Syringe Refill [A2]	00817441020739
004-101A3	VLC Flowable Composite 2 g Syringe Refill [A3]	00817441020531
004-101A3.5	VLC Flowable Composite 2 g Syringe Refill [A3.5]	00817441020548
004-101A4	VLC Flowable Composite 2 g Syringe Refill [A4]	00817441020555
004-101B1	VLC Flowable Composite 2 g Syringe Refill [B1]	00817441020562
004-101B2	VLC Flowable Composite 2 g Syringe Refill [B2]	00817441020579
004-101B3	VLC Flowable Composite 2 g Syringe Refill [B3]	00817441020586
004-101B4	VLC Flowable Composite 2 g Syringe Refill [B4]	00817441020593
004-101C1	VLC Flowable Composite 2 g Syringe Refill [C1]	00817441020609
004-101C2	VLC Flowable Composite 2 g Syringe Refill [C2]	00817441020616
004-101C3	VLC Flowable Composite 2 g Syringe Refill [C3]	00817441020623
004-101C4	VLC Flowable Composite 2 g Syringe Refill [C4]	00817441020630
004-101D2	VLC Flowable Composite 2 g Syringe Refill [D2]	00817441020647
004-101D3	VLC Flowable Composite 2 g Syringe Refill [D3]	00817441020654
004-101D4	VLC Flowable Composite 2 g Syringe Refill [D4]	00817441020661
004-101I	VLC Flowable Composite 2 g Syringe Refill [Incisal]	00817441020678
004-101O	VLC Flowable Composite 2 g Syringe Refill [Opaque]	00817441020685
004-101OA2	VLC Flowable Composite 2 g Syringe Refill [OA2]	00817441020692
004-101OA3	VLC Flowable Composite 2 g Syringe Refill [OA3]	00817441020708
004-101OA3.5	VLC Flowable Composite 2 g Syringe Refill [OA3.5]	00817441020715
	<b>Prime-Dent Esthetic Kit</b>	
001-420	Esthetic Kit Micro-Hybrid, Hybrid, Flowable, Sealant, Bonding Resin, Desensitizer, Etchant Gel and accessories all in one kit for cosmetic restoration	00817441024904
	<b>Parafil</b>	
9999-9000	Parafil Restorative Composite 8 Syringe Kit	00817441021323
9999-9001	Parafil Restorative Composite 4 Syringe Kit	00817441021330
9999-9002	Parafil Restorative Composite 2 Syringe Kit	00817441021347
9999-90A1	Parafil Restorative Composite 4.5 g Syringe Refill [A1]	00817441021019
9999-90A2	Parafil Restorative Composite 4.5 g Syringe Refill [A2]	00817441021026
9999-90A3	Parafil Restorative Composite 4.5 g Syringe Refill [A3]	00817441021033
9999-90A3.5	Parafil Restorative Composite 4.5 g Syringe Refill [A3.5]	00817441021040
9999-90A4	Parafil Restorative Composite 4.5 g Syringe Refill [A4]	00817441021057
9999-90B1	Parafil Restorative Composite 4.5 g Syringe Refill [B1]	00817441021064
9999-90B2	Parafil Restorative Composite 4.5 g Syringe Refill [B2]	00817441021071
9999-90B3	Parafil Restorative Composite 4.5 g Syringe Refill [B3]	00817441021088
9999-90B4	Parafil Restorative Composite 4.5 g Syringe Refill [B4]	00817441021095
9999-90C1	Parafil Restorative Composite 4.5 g Syringe Refill [C1]	00817441021101
9999-90C2	Parafil Restorative Composite 4.5 g Syringe Refill [C2]	00817441021118
9999-90C3	Parafil Restorative Composite 4.5 g Syringe Refill [C3]	00817441021125
9999-90C4	Parafil Restorative Composite 4.5 g Syringe Refill [C4]	00817441021132
9999-90D2	Parafil Restorative Composite 4.5 g Syringe Refill [D2]	00817441021149



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9999-90D3	Parafil Restorative Composite 4.5 g Syringe Refill [D3]	00817441021156
9999-90D4	Parafil Restorative Composite 4.5 g Syringe Refill [D4]	00817441021163
9999-90OP	Parafil Restorative Composite 4.5 g Syringe Refill [Opaque]	00817441024911
9999-90INC	Parafil Restorative Composite 4.5 g Syringe Refill [Incisal]	00817441024928
9999-90OA2	Parafil Restorative Composite 4.5 g Syringe Refill [OA2]	00817441021170
9999-90OA3	Parafil Restorative Composite 4.5 g Syringe Refill [OA3]	00817441021187
9999-90OA3.5	Parafil Restorative Composite 4.5 g Syringe Refill [OA3.5]	00817441021194
9999-90OA4	Parafil Restorative Composite 4.5 g Syringe Refill [OA4]	00817441021200
9999-90UO	Parafil Restorative Composite 4.5 g Syringe Refill [Universal Opaque]	00817441021217
9999-90UD	Parafil Restorative Composite 4.5 g Syringe Refill [Universal Dentin]	00817441021224
9999-90DT	Parafil Restorative Composite 4.5 g Syringe Refill [Dark Translucent]	00817441021231
9999-90CT	Parafil Restorative Composite 4.5 g Syringe Refill [Clear Translucent]	00817441021248
9999-90NT	Parafil Restorative Composite 4.5 g Syringe Refill [Natural Translucent]	00817441021255
9999-90ET4	Parafil Restorative Composite 4.5 g Syringe Refill [ET4]	00817441021262
9999-90IB	Parafil Restorative Composite 4.5 g Syringe Refill [Incisal Blue]	00817441021279
9999-90IU	Parafil Restorative Composite 4.5 g Syringe Refill [Incisal Universal]	00817441021286
9999-90IY	Parafil Restorative Composite 4.5 g Syringe Refill [Incisal Yellow]	00817441021293
9999-90OTB	Parafil Restorative Composite 4.5 g Syringe Refill [OTB]	00817441021309
9999-90OTG	Parafil Restorative Composite 4.5 g Syringe Refill [OTG]	00817441021316
9999-90BW	Parafil Restorative Composite 4.5 g Syringe Refill [BW]	00817441024935
9999-90EXWL	Parafil Restorative Composite 4.5 g Syringe Refill [EXWL]	00817441024942
9999-90DXWL	Parafil Restorative Composite 4.5 g Syringe Refill [DXWL]	00817441024959
9999-90HW	Parafil Restorative Composite 4.5 g Syringe Refill [HOLLYWOOD WHITE]	00817441024966
9999-90FOU	Parafil Restorative Composite 4.5 g Syringe Refill [FOU]	00817441024973
9999-90MO	Parafil Restorative Composite 4.5 g Syringe Refill [MO]	00817441024980
9999-91A1	Parafil Restorative Composite 20 Compules x .20 g each [A1]	00817441024997
9999-91A2	Parafil Restorative Composite 20 Compules x .20 g each [A2]	00817441025000
9999-91A3	Parafil Restorative Composite 20 Compules x .20 g each [A3]	00817441025017
9999-91A3.5	Parafil Restorative Composite 20 Compules x .20 g each [A3.5]	00817441025024
9999-91A4	Parafil Restorative Composite 20 Compules x .20 g each [A4]	00817441025031
9999-91B1	Parafil Restorative Composite 20 Compules x .20 g each [B1]	00817441025048
9999-91B2	Parafil Restorative Composite 20 Compules x .20 g each [B2]	00817441025055
9999-91B3	Parafil Restorative Composite 20 Compules x .20 g each [B3]	00817441025062
9999-91B4	Parafil Restorative Composite 20 Compules x .20 g each [B4]	00817441025079
9999-91C1	Parafil Restorative Composite 20 Compules x .20 g each [C1]	00817441025086
9999-91C2	Parafil Restorative Composite 20 Compules x .20 g each [C2]	00817441025093
9999-91C3	Parafil Restorative Composite 20 Compules x .20 g each [C3]	00817441025109
9999-91C4	Parafil Restorative Composite 20 Compules x .20 g each [C4]	00817441025116
9999-91D2	Parafil Restorative Composite 20 Compules x .20 g each [D2]	00817441025123
9999-91D3	Parafil Restorative Composite 20 Compules x .20 g each [D3]	00817441025130
9999-91D4	Parafil Restorative Composite 20 Compules x .20 g each [D4]	00817441025147
9999-91OP	Parafil Restorative Composite 20 Compules x .20 g each [Opaque]	00817441025154
9999-91INC	Parafil Restorative Composite 20 Compules x .20 g each [Incisal]	00817441025161
9999-91OA2	Parafil Restorative Composite 20 Compules x .20 g each [OA2]	00817441025178
9999-91OA3	Parafil Restorative Composite 20 Compules x .20 g each [OA3]	00817441025185
9999-91OA3.5	Parafil Restorative Composite 20 Compules x .20 g each [OA3.5]	00817441025192
9999-91OA4	Parafil Restorative Composite 20 Compules x .20 g each [OA4]	00817441025208
9999-91UO	Parafil Restorative Composite 20 Compules x .20 g each [Universal Opaque]	00817441025215
9999-91UD	Parafil Restorative Composite 20 Compules x .20 g each [Universal Dentin]	00817441025222
9999-91DT	Parafil Restorative Composite 20 Compules x .20 g each [Dark Translucent]	00817441025239
9999-91CT	Parafil Restorative Composite 20 Compules x .20 g each [Clear Translucent]	00817441025246
9999-91NT	Parafil Restorative Composite 20 Compules x .20 g each [Natural Translucent]	00817441025253
9999-91ET4	Parafil Restorative Composite 20 Compules x .20 g each [ET4]	00817441025260
9999-91IB	Parafil Restorative Composite 20 Compules x .20 g each [Incisal Blue]	00817441025277
9999-91IU	Parafil Restorative Composite 20 Compules x .20 g each [Incisal Universal]	00817441025284



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9999-91IY	Parafil Restorative Composite 20 Compules x .20 g each [Incisal Yellow]	00817441025291
9999-91OTB	Parafil Restorative Composite 20 Compules x .20 g each [OTB]	00817441025307
9999-91OTG	Parafil Restorative Composite 20 Compules x .20 g each [OTG]	00817441025314
9999-91BW	Parafil Restorative Composite 20 Compules x .20 g each [BW]	00817441025321
9999-91EXWL	Parafil Restorative Composite 20 Compules x .20 g each [EXWL]	00817441025338
9999-91DXWL	Parafil Restorative Composite 20 Compules x .20 g each [DXWL]	00817441025345
9999-91HW	Parafil Restorative Composite 20 Compules x .20 g each [HOLLYWOOD WHITE]	00817441025352
9999-91FOU	Parafil Restorative Composite 20 Compules x .20 g each [FOU]	00817441025369
9999-91MO	Parafil Restorative Composite 20 Compules x .20 g each [MO]	00817441025376
	<b>Parafil LAB</b>	
9999-7000	Parafil LAB Restorative Composite 10 Syringe Kit	00817441021668
9999-7001	Parafil LAB Restorative Composite 4 Syringe Kit	00817441021675
9999-70A1	Parafil LAB Restorative Composite 4.5 g Syringe Refill [A1]	00817441021354
9999-70A2	Parafil LAB Restorative Composite 4.5 g Syringe Refill [A2]	00817441021361
9999-70A3	Parafil LAB Restorative Composite 4.5 g Syringe Refill [A3]	00817441021378
9999-70A3.5	Parafil LAB Restorative Composite 4.5 g Syringe Refill [A3.5]	00817441021385
9999-70A4	Parafil LAB Restorative Composite 4.5 g Syringe Refill [A4]	00817441021392
9999-70B1	Parafil LAB Restorative Composite 4.5 g Syringe Refill [B1]	00817441021408
9999-70B2	Parafil LAB Restorative Composite 4.5 g Syringe Refill [B2]	00817441021415
9999-70B3	Parafil LAB Restorative Composite 4.5 g Syringe Refill [B3]	00817441021422
9999-70B4	Parafil LAB Restorative Composite 4.5 g Syringe Refill [B4]	00817441021439
9999-70C1	Parafil LAB Restorative Composite 4.5 g Syringe Refill [C1]	00817441021446
9999-70C2	Parafil LAB Restorative Composite 4.5 g Syringe Refill [C2]	00817441021453
9999-70C3	Parafil LAB Restorative Composite 4.5 g Syringe Refill [C3]	00817441021460
9999-70C4	Parafil LAB Restorative Composite 4.5 g Syringe Refill [C4]	00817441021477
9999-70D2	Parafil LAB Restorative Composite 4.5 g Syringe Refill [D2]	00817441021484
9999-70D3	Parafil LAB Restorative Composite 4.5 g Syringe Refill [D3]	00817441021491
9999-70D4	Parafil LAB Restorative Composite 4.5 g Syringe Refill [D4]	00817441021507
9999-70OA2	Parafil LAB Restorative Composite 4.5 g Syringe Refill [OA2]	00817441021514
9999-70OA3	Parafil LAB Restorative Composite 4.5 g Syringe Refill [OA3]	00817441021521
9999-70OA3.5	Parafil LAB Restorative Composite 4.5 g Syringe Refill [OA3.5]	00817441021538
9999-70OA4	Parafil LAB Restorative Composite 4.5 g Syringe Refill [OA4]	00817441021545
9999-70UO	Parafil LAB Restorative Composite 4.5 g Syringe Refill [Universal Opaque]	00817441021552
9999-70UD	Parafil LAB Restorative Composite 4.5 g Syringe Refill [Universal Dentin]	00817441021569
9999-70DT	Parafil LAB Restorative Composite 4.5 g Syringe Refill [Dark Translucent]	00817441021576
9999-70CT	Parafil LAB Restorative Composite 4.5 g Syringe Refill [Clear Translucent]	00817441021583
9999-70NT	Parafil LAB Restorative Composite 4.5 g Syringe Refill [Natural Translucent]	00817441021590
9999-70ET4	Parafil LAB Restorative Composite 4.5 g Syringe Refill [ET4]	00817441021606
9999-70IB	Parafil LAB Restorative Composite 4.5 g Syringe Refill [Incisal Blue]	00817441021613
9999-70IU	Parafil LAB Restorative Composite 4.5 g Syringe Refill [Incisal Universal]	00817441021620
9999-70IY	Parafil LAB Restorative Composite 4.5 g Syringe Refill [Incisal Yellow]	00817441021637
9999-70OTB	Parafil LAB Restorative Composite 4.5 g Syringe Refill [OTB]	00817441021644
9999-70OTG	Parafil LAB Restorative Composite 4.5 g Syringe Refill [OTG]	00817441021651
9999-70IN	Parafil LAB Restorative Composite 4.5 g Syringe Refill [Incisal]	00817441025383
9999-70OP	Parafil LAB Restorative Composite 4.5 g Syringe Refill [Opaque]	00817441025390
9999-70BW	Parafil LAB Restorative Composite 4.5 g Syringe Refill [BW]	00817441025406
9999-70EXWL	Parafil LAB Restorative Composite 4.5 g Syringe Refill [EXWL]	00817441025413
9999-70DXWL	Parafil LAB Restorative Composite 4.5 g Syringe Refill [DXWL]	00817441025420
9999-70HW	Parafil LAB Restorative Composite 4.5 g Syringe Refill [HOLLYWOOD WHITE]	00817441025437
9999-70FOU	Parafil LAB Restorative Composite 4.5 g Syringe Refill [FOU]	00817441025444
9999-70MO	Parafil LAB Restorative Composite 4.5 g Syringe Refill [MO]	00817441025451
9999-71A1	Parafil LAB Restorative Composite 20 Compules x .20 g each [A1]	00817441025468
9999-71A2	Parafil LAB Restorative Composite 20 Compules x .20 g each [A2]	00817441025475
9999-71A3	Parafil LAB Restorative Composite 20 Compules x .20 g each [A3]	00817441025482



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9999-71A3.5	Parafil LAB Restorative Composite 20 Compules x .20 g each [A3.5]	00817441025499
9999-71A4	Parafil LAB Restorative Composite 20 Compules x .20 g each [A4]	00817441025505
9999-71B1	Parafil LAB Restorative Composite 20 Compules x .20 g each [B1]	00817441025512
9999-71B2	Parafil LAB Restorative Composite 20 Compules x .20 g each [B2]	00817441025529
9999-71B3	Parafil LAB Restorative Composite 20 Compules x .20 g each [B3]	00817441025536
9999-71B4	Parafil LAB Restorative Composite 20 Compules x .20 g each [B4]	00817441025543
9999-71C1	Parafil LAB Restorative Composite 20 Compules x .20 g each [C1]	00817441025550
9999-71C2	Parafil LAB Restorative Composite 20 Compules x .20 g each [C2]	00817441025567
9999-71C3	Parafil LAB Restorative Composite 20 Compules x .20 g each [C3]	00817441025574
9999-71C4	Parafil LAB Restorative Composite 20 Compules x .20 g each [C4]	00817441025581
9999-71D2	Parafil LAB Restorative Composite 20 Compules x .20 g each [D2]	00817441025598
9999-71D3	Parafil LAB Restorative Composite 20 Compules x .20 g each [D3]	00817441025604
9999-71D4	Parafil LAB Restorative Composite 20 Compules x .20 g each [D4]	00817441025611
9999-71OA2	Parafil LAB Restorative Composite 20 Compules x .20 g each [OA2]	00817441025628
9999-71OA3	Parafil LAB Restorative Composite 20 Compules x .20 g each [OA3]	00817441025635
9999-71OA3.5	Parafil LAB Restorative Composite 20 Compules x .20 g each [OA3.5]	00817441025642
9999-71OA4	Parafil LAB Restorative Composite 20 Compules x .20 g each [OA4]	00817441025659
9999-71UO	Parafil LAB Restorative Composite 20 Compules x .20 g each [Universal Opaque]	00817441025666
9999-71UD	Parafil LAB Restorative Composite 20 Compules x .20 g each [Universal Dentin]	00817441025673
9999-71DT	Parafil LAB Restorative Composite 20 Compules x .20 g each [Dark Translucent]	00817441025680
9999-71CT	Parafil LAB Restorative Composite 20 Compules x .20 g each [Clear Translucent]	00817441025697
9999-71NT	Parafil LAB Restorative Composite 20 Compules x .20 g each [Natural Translucent]	00817441025703
9999-71ET4	Parafil LAB Restorative Composite 20 Compules x .20 g each [ET4]	00817441025710
9999-71IB	Parafil LAB Restorative Composite 20 Compules x .20 g each [Incisal Blue]	00817441025727
9999-71IU	Parafil LAB Restorative Composite 20 Compules x .20 g each [Incisal Universal]	00817441025734
9999-71IY	Parafil LAB Restorative Composite 20 Compules x .20 g each [Incisal Yellow]	00817441025741
9999-71OTB	Parafil LAB Restorative Composite 20 Compules x .20 g each [OTB]	00817441025758
9999-71OTG	Parafil LAB Restorative Composite 20 Compules x .20 g each [OTG]	00817441025765
9999-71INC	Parafil LAB Restorative Composite 20 Compules x .20 g each [Incisal]	00817441025772
9999-71OP	Parafil LAB Restorative Composite 20 Compules x .20 g each [Opaque]	00817441025789
9999-71BW	Parafil LAB Restorative Composite 20 Compules x .20 g each [BW]	00817441025796
9999-71EXWL	Parafil LAB Restorative Composite 20 Compules x .20 g each [EXWL]	00817441025802
9999-71DXWL	Parafil LAB Restorative Composite 20 Compules x .20 g each [DXWL]	00817441025819
9999-71HW	Parafil LAB Restorative Composite 20 Compules x .20 g each [HOLLYWOOD WHITE]	00817441025826
9999-71FOU	Parafil LAB Restorative Composite 20 Compules x .20 g each [FOU]	00817441025833
9999-71MO	Parafil LAB Restorative Composite 20 Compules x .20 g each [MO]	00817441025840
9999-7250	Parafil Modifier 7 ml Bottle	00817441021736
9999-7260	Parafil Modeler 7 ml Bottle	00817441021743
9999-7240	Parafil Separator 3 g Syringe	00817441021712
9999-7241	Parafil Separator 10 g Syringe	00817441021729
	<b>Parafil Gingiva</b>	
9999-7100	Parafil Gingiva 8 Syringe Kit	00817441021750
9999-GM21	Parafil Gingiva Modifier 2 g Syringe Refill [GM21]	00817441021767
9999-GM22	Parafil Gingiva Modifier 2 g Syringe Refill [GM22]	00817441021774
9999-GM23	Parafil Gingiva Modifier 2 g Syringe Refill [GM23]	00817441021781
9999-9G21	Parafil Gingiva Body 4.5 g Syringe Refill [G21]	00817441021798
9999-9G22	Parafil Gingiva Body 4.5 g Syringe Refill [G22]	00817441021804
9999-9G23	Parafil Gingiva Body 4.5 g Syringe Refill [G23]	00817441021811





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9999-GO12	Parafil Gingiva Opaque 2 g Syringe Refill	00817441021828
9999-GOM2	Parafil Gingiva Opaque Modifier 2 g Syringe Refill	00817441021835
	<b>Parafil Stains</b>	
9999-7300	Parafil Stain 8 Syringe Kit	00817441021842
9999-71BE	Parafil Stain 1.6 g Syringe Refill [Beige]	00817441021859
9999-71BL	Parafil Stain 1.6 g Syringe Refill [Blue]	00817441021866
9999-71BR	Parafil Stain 1.6 g Syringe Refill [Brown]	00817441021873
9999-71YE	Parafil Stain 1.6 g Syringe Refill [Yellow]	00817441021880
9999-71WH	Parafil Stain 1.6 g Syringe Refill [White]	00817441021897
9999-71OR	Parafil Stain 1.6 g Syringe Refill [Orange]	00817441021903
9999-71GR	Parafil Stain 1.6 g Syringe Refill [Gray]	00817441021910
9999-71PI	Parafil Stain 1.6 g Syringe Refill [Pink]	00817441021927
	<b>Prime-Dent Chemical Cure Composite</b>	
002-017	Chemical Cure Composite Kit 30g/30g	00817441021965
002-018	Chemical Cure Composite Kit 30g/30g w/bonding	00817441021958
002-011	Chemical Cure Composite Kit 15g/15g	00817441021941
002-012	Chemical Cure Composite Kit 15g/15g w/bonding	00817441021934
002-004	Chemical Cure Composite Kit 7g/7g	00817441021989
002-005	Chemical Cure Composite Kit 7g/7g w/bonding	00817441021972
002-003	Chemical Cure Composite Kit 5g/5g	00817441022009
002-002	Chemical Cure Composite Kit 5g/5g w/bonding	00817441021996
002-001	Chemical Cure Composite Kit 3g/3g	00817441022023
002-001B	Chemical Cure Composite Kit 3g/3g w/bonding	00817441022016
002-022	Chemical Cure Composite Kit 1.5g/1.5g	00817441022047
002-023	Chemical Cure Composite Kit 1.5g/1.5g w/bonding	00817441022030
002-050	Chemical Cure Composite Catalyst Paste 15 g Jar Refill	00817441025857
002-051	Chemical Cure Composite Base Paste 15 g Jar Refill	00817441025864
002-052	Chemical Cure Composite Catalyst Paste 30 g Jar Refill	00817441025871
002-053	Chemical Cure Composite Base Paste 30 g Jar Refill	00817441025888
002-054	Chemical Cure Composite Catalyst Paste 7 g Jar Refill	00817441025895
002-055	Chemical Cure Composite Base Paste 7 g Jar Refill	00817441025901
002-056	Chemical Cure Composite Catalyst Paste 5 g Jar Refill	00817441025918
002-057	Chemical Cure Composite Base Paste 5 g Jar Refill	00817441025925
002-058	Chemical Cure Composite Catalyst Paste 3 g Jar Refill	00817441025932
002-059	Chemical Cure Composite Base Paste 3 g Jar Refill	00817441025949

**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 Bonding Agent

Parafil Primer

Prime-Dent Light Cure Surface Sealant



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ITEM NUMBER	DESCRIPTION	UDI
	<b>Prime-Dent Light Cure One-Step Dentin/Enamel Bonding Adhesive</b>	
006-030	Prime-Dent Light Cure One-Step Dentin/Enamel Bonding Adhesive 7 ml Bottle	00817441022658
006-032	Prime-Dent Light Cure One-Step Dentin/Enamel Bonding Adhesive 3 ml Bottle	00817441022665
	<b>Prime-Dent Light Cure Dentin/Enamel Bonding Adhesive</b>	
006-020	VLC Dentin/Enamel Bonding Kit (2-3ml bond, 7.5ml etch)	
006-018	VLC Dentin/Enamel Bonding Adhesive 3ml Bottle	00817441022689
006-019	VLC Dentin/Enamel Bonding Adhesive 7 ml Bottle	00817441022672
	<b>Prime-Dent Chemical Cure Dentin/Enamel Bonding Adhesive</b>	
006-021	Chemical Cure Dentin/Enamel Bonding (2-3ml bond, 7.5ml etch)	00817441022696
006-024	Chemical Cure Dentin/Enamel Bonding Base 3 ml Bottle	00817441022719
006-025	Chemical Cure Dentin/Enamel Bonding Catalyst 3 ml Bottle	00817441022702
	<b>Prime-Dent Light Cure Self Etch Bonding Agent</b>	
006-033	Self Etch Bonding Agent 7 ml Bottle	00817441025956
	<b>Parafil Primer</b>	
9999-7220	Parafil Metal Primer 7 ml Bottle	00817441021699
9999-7230	Parafil Composite Primer 7 ml Bottle	00817441021705
	<b>Prime-Dent Light Cure Surface Sealant</b>	
005-010	VLC Composite Surface Sealant 7ml Bottle	00817441022788
005-011	VLC Composite Surface Sealant 3ml Bottle	00817441022795

**Type of Product: Dental Cements**

**Technical File No.: TF03**

Class: IIa, Rule 8

Product Names:

Prime-Dent Glass Ionomer Powder/Liquid Cement

Prime-Dent Zinc Oxide Eugenol Cement

Prime-Dent Zinc Phosphate Cement

Prime-Dent Polycarboxylate Cement

Prime-Dent Glass Ionomer Restorative

ITEM NUMBER	DESCRIPTION	UDI
	<b>Prime-Dent Glass Ionomer Powder/Liquid Cement</b>	
010-020	Glass Ionomer Cement Kit 18 g Powder/17.5ml Liquid	00817441022115
010-023	Glass Ionomer Cement Kit 10 g Powder/6 ml Liquid	00817441022122
010-021	Glass Ionomer Cement 18gm Powder Refill	00817441022139



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010-022	Glass Ionomer Cement 17.5ml Liquid Refill	00817441022146
	<b>Prime-Dent Zinc Oxide Eugenol Cement</b>	
010-080	Zinc Oxide Eugenol Cement Kit	00817441022597
010-081	Zinc Oxide Eugenol Cement Powder 21 g Jar	00817441022603
010-082	Zinc Oxide Eugenol Cement Liquid 7.5 ml Bottle	00817441022610
010-090	Zinc Oxide Eugenol Cement Reinforced Material (w/Fiber) Kit	00817441022627
010-091	Zinc Oxide Eugenol Cement Reinforced Material Powder 50 g Jar	00817441022634
010-092	Zinc Oxide Eugenol Cement Reinforced Material Liquid 15 ml Bottle	00817441022641
	<b>Prime-Dent Zinc Phosphate Cement</b>	
010-030	Zinc Phosphate Cement Kit	00817441022238
010-028	Zinc Phosphate Cement Powder Refill 32 g	00817441022245
010-029	Zinc Phosphate Cement Liquid Refill 17.5	00817441022252
	<b>Prime-Dent Polycarboxylate Cement</b>	
010-036	PCA Cement Kit	00817441022207
010-025	PCA Cement Powder Refill 32 g	00817441022214
010-027	PCA Cement Liquid Refill 17.5 ml	00817441022221
	<b>Prime-Dent Glass Ionomer Restorative</b>	
010-060	GI Restorative Kit 18/17.5	00817441022054
010-061	GI Restorative Kit 10/6	00817441022061
010-062	GI Restorative 18 g Powder Refill	00817441022078
010-063	GI Restorative 17.5 ml Liquid Refill	00817441022085
010-064	GI Restorative 10 g Powder Refill	00817441022092
010-065	GI Restorative 6 ml Liquid Refill	00817441022108

**Type of Product: Dental Polymer Based Luting Cements**

**Technical File No.: TF04**

Class: IIa, Rule 8

Product Names: Prime-Dent Dual Cure Composite Luting Cement

Prime Dent Automix System Dual Cure Composite Luting Cement

ITEM NUMBER	DESCRIPTION	UDI
	<b>Prime-Dent Dual Cure Composite Luting Cement</b>	
100-100	Automix Dual Cure Composite Luting Cement 4-10 g Syrs. Kit Shade A2	00817441022382
100-110	Automix Dual Cure Composite Luting Cement 4-10 g Syrs. Kit Shade A4	00817441022399
100-112	Automix Dual Cure Composite Luting Cement 4-10 g Syrs. Kit Shade Blue	00817441022405
100-119	Automix Dual Cure Composite Luting Cement 4-10 g Syrs. Kit Shade White Opaque	00817441022412
100-114	Automix Dual Cure Composite Luting Cement 2-10 g Syrs. Kit Shade A2	00817441022429
100-115	Automix Dual Cure Composite Luting Cement 2-10 g Syrs. Kit Shade A4	00817441022436
100-116	Automix Dual Cure Composite Luting Cement 2-10 g Syrs. Kit Shade Blue	00817441022443
100-120	Automix Dual Cure Composite Luting Cement 2-10 g Syrs. Kit Shade White Opaque	00817441022450
100-101	Automix Dual Cure Composite Luting Cement 1-10 g Syr. Kit Shade A2	00817441022467
100-111	Automix Dual Cure Composite Luting Cement 1-10 g Syr. Kit Shade A4	00817441022474
100-113	Automix Dual Cure Composite Luting Cement 1-10 g Syr. Kit Shade Blue	00817441022481
100-121	Automix Dual Cure Composite Luting Cement 1-10 g Syr. Kit Shade White Opaque	00817441022498
015-022	Dual Cure Composite Luting Cement Kit 2-5 g Catalyst Syr., 2-5 g Base Syr.	00817441025963



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	3ml Base Bond Resin, 3ml Base Bond Resin, 4g Etch Gel Syr., Accessories	
009-021	Dual Cure Composite Luting Cement Kit 2-5 g Syringes	
100-102	Automix Dual Cure Composite Luting Cement 10 g Syringe Refill Shade A2	00817441022504
100-117	Automix Dual Cure Composite Luting Cement 10 g Syringe Refill Shade A4	00817441022511
100-118	Automix Dual Cure Composite Luting Cement 10 g Syringe Refill Shade Blue	00817441022528
100-122	Automix Dual Cure Composite Luting Cement 10 g Syringe Refill Shade White Opaque	00817441022535
009-022	Dual Cure Composite Luting Cement Base 5 g Refill Syringe	00817441025970
009-023	Dual Cure Composite Luting Cement Catalyst 5 g Refill Syringe	00817441025987
003-046	PDM Brown Mixing Tips & 25 Intra Oral Tips 25&25/Bag	00817441025994
003-047	Sulzer Mixpax Brown Mixing Tips & 25 Fine Intra Oral Tips 25&25/Bag	00817441026007

**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

ITEM NUMBER	DESCRIPTION	UDI
	<b>Prime-Dent Chemical Cure Core Build-Up Material</b>	
003-018	Chemical Cure Core Build-Up Material Kit 15gm/15gm White	00817441023556
003-019	Chemical Cure Core Build-Up Material Kit 15gm/15gm Blue	00817441026014
003-020	Chemical Cure Core Build-Up Material Kit 15gm/15gm Natural	00817441026021
	<b>Prime-Dent Light Cure Core Build-Up Material</b>	
003-021	Light Cure Core Build-Up Material 5gm Syringe Contrast Blue Shade	00817441023624
003-022	Light Cure core Build-Up Material 5gm Syringe Natural Shade	00817441023617
	<b>Prime-Dent Automix Dual Cure Core Build-Up Material</b>	
003-060	Prime-Core D/C Automix Cartridge w/20 Canulas & 20 Intra Oral Tips Natural	00817441026144
003-061	Prime-Core D/C Automix Cartridge w/20 Canulas & 20 Intra Oral Tips Blue	00817441023563
003-080	Prime-Core D/C Automix Syringes 4 Syringe Kit (A2)	00817441026038
003-081	Prime-Core D/C Automix Syringes 2 Syringe Kit (A2)	00817441026045
003-082	Prime-Core D/C Automix Syringes 1 Syringe Kit (A2)	00817441026052
003-083	Prime-Core D/C Automix Syringes 4 Syringe Kit (Blue)	00817441026069
003-084	Prime-Core D/C Automix Syringes 2 Syringe Kit (Blue)	00817441026076
003-085	Prime-Core D/C Automix Syringes 1 Syringe Kit (Blue)	00817441026083
003-062	Automix Dual Cure Core Build-Up Material 50gm Natural Refill	00817441023570
003-063	Automix Dual Cure Core Build-Up Material 50gm Blue Refill	00817441023587
003-086	Prime-Core D/C Automix Syringe Refill 10 g (A2) [no mixing tips]	00817441023600
003-087	Prime-Core D/C Automix Syringe Refill 10 g (Blue) [no mixing tips]	00817441023594
003-040	PDM 25 ml 1:1/1:2 Dispensing Gun	00817441026090
003-041	PDM Yellow Mixing Tips 50/Bag	00817441026106
003-042	PDM Yellow Intra Oral Tips 50/Bag	00817441026113
003-046	PDM Brown Mixing Tips & 25 Intra Oral Tips 25&25/Bag	00817441026120





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003-047	PDM Brown Mixing Tips & 25 Fine Intra Oral Tips 25&25/Bag	00817441026137
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**Type of Product: Dental Root Canal Filling Materials**  
**Technical File No.: TF06**  
 Class: IIa, Rule 8  
 Product Names: Prime-Dent Root Canal Filling Material

ITEM NUMBER	DESCRIPTION	UDI
	<b>Prime-Dent Root Canal Filling Material</b>	
022-010	Root Canal Filling Material 8gm Powder/10 gm Resin	00817441023341
022-011	Root Canal Filling Material 8gm Powder Refill	00817441023358
022-012	Root Canal Filling Material 10gm Liquid Refill	00817441023365

**Type of Product: Dental Temporary Cements**  
**Technical File No.: TF07**  
 Class: IIa, Rule 5  
 Product Names: Prime-Dent Resin Based Non-Eugenol Temporary Cement

ITEM NUMBER	DESCRIPTION	UDI
	<b>Prime-Dent Resin Based Non-Eugenol Temporary Cement</b>	
023-009	Non Eugenol Temporary Cement 15/15gm Kit	00817441026595
023-010	Automix Non Eugenol Temporary Cement 32gm Kit w/mixing accessories	00817441022184
023-012	Automix Non Eugenol Temporary Cement Kit 1 x 6 gm Syr. & 5 Mixing Tips	00817441022160
023-013	Automix Non Eugenol Temporary Cement Kit 4 x 6 gm Syrs. & 20 Mixing Tips	00817441022153
023-007	Non Eugenol Temporary Cement 15gm Base Paste Jar Refill	
023-008	Non Eugenol Temporary Cement 15gm Catalyst Paste Jar Refill	
023-011	Automix Non Eugenol Temporary Cement 32gm Cartridge Refill	00817441022191
023-014	Automix Non Eugenol Temporary Cement Syringe Refill 6gm	00817441022177
003-040	PDM 25 ml 1:1/1:2 Dispensing Gun	00817441026090
003-041	PDM Yellow Mixing Tips 50/Bag	00817441026106
003-042	PDM Yellow Intra Oral Tips 50/Bag	00817441026113
003-044	PDM Blue Mixing Tips 25/Bag	00817441026151

**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 Porcelain Etchant

ITEM NUMBER	DESCRIPTION	UDI
	<b>Prime-Dent Etchant Gel</b>	



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008-010	Etch Gel Syringe Kit 4-1.2 ml Syringes w/8 tips 37% Blue	00817441022818
008-011	Etch Gel Syringe Kit 4-1.2 ml Syringes w/8 tips 37% Green	00817441022832
008-012	Etch Gel Syringe Pack 20-1.2 ml Syringes w/40 tips 37% Blue	00817441022856
008-013	Etch Gel Syringe Pack 20-1.2 ml Syringes w/40 tips 37% Green	00817441022870
008-020	Etch Gel Syringe Kit 4-4 g Syringes w/20 tips 37% Blue	00817441026182
008-021	Etch Gel Syringe Kit 4-4 g Syringes w/20 tips 37% Green	00817441026199
008-060	Etch Gel Syringe 50 ml w/50 tips, 3-4 ml dispensing syrs. w/coupler 37% Blue	00817441022894
008-061	Etch Gel Syringe 50 ml w/50 tips, 3-4 ml dispensing syrs. w/coupler 37% Green	00817441022917
008-030	Etch Gel Syringe 12 g w/5 tips 37% Blue	00817441022931
008-031	Etch Gel Syringe 12 g w/5 tips 37% Green	00817441022955
008-035	Etch Gel Bottle 8 oz. 37% Blue	00817441023051
008-036	Etch Gel Bottle 8 oz. 37% Green	00817441023075
008-062	Etch Gel Syringe 50 ml 37% Blue	00817441022894
008-063	Etch Gel Syringe 50 ml 37% Green	00817441022917
008-070	Etch Gel Syringe 4 g w/5 tips 37% Blue	00817441023013
008-071	Etch Gel Syringe 4 g w/5 tips 37% Green	00817441023037
008-072	Etch Gel Syringe 1.2 ml w/3 tips 37% Blue	00817441022979
008-073	Etch Gel Syringe 1.2 ml w/3 tips 37% Green	00817441022993
008-042	Etch Gel Bottle (Oval) 7.5 ml 37% Blue	00817441023099
008-043	Etch Gel Bottle (Oval) 7.5 ml 37% Green	00817441023112
	<b>Prime-Dent Etchant Gel Silica Free</b>	
008-010SF	Silica-Free Etch Gel Syringe Kit 4-1.2 ml Syringes w/8 tips 37% Blue	00817441022825
008-011SF	Silica-Free Etch Gel Syringe Kit 4-1.2 ml Syringes w/8 tips 37% Green	00817441022849
008-012SF	Silica-Free Etch Gel Syringe Pack 20-1.2 ml Syringes w/40 tips 37% Blue	00817441022863
008-013SF	Silica-Free Etch Gel Syringe Pack 20-1.2 ml Syringes w/40 tips 37% Green	00817441022887
008-020SF	Silica-Free Etch Gel Syringe Kit 4-4 g Syringes w/20 tips 37% Blue	00817441026168
008-021SF	Silica-Free Etch Gel Syringe Kit 4-4 g Syringes w/20 tips 37% Green	00817441026175
008-060SF	Silica-Free Etch Gel Syringe 50 ml w/50 tips, 3-4 ml dispensing syrs. w/coupler 37% Blue	00817441022900
008-061SF	Silica-Free Etch Gel Syringe 50 ml w/50 tips, 3-4 ml dispensing syrs. w/coupler 37% Green	00817441022924
008-030SF	Silica-Free Etch Gel Syringe 12 g w/5 tips 37% Blue	00817441022948
008-031SF	Silica-Free Etch Gel Syringe 12 g w/5 tips 37% Green	00817441022962
008-035SF	Silica-Free Etch Gel Bottle 8 oz. 37% Blue	00817441023068



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008-036SF	Silica-Free Etch Gel Bottle 8 oz. 37% Green	00817441023082
008-062SF	Silica-Free Etch Gel Syringe 50 ml 37% Blue	00817441022900
008-063SF	Silica-Free Etch Gel Syringe 50 ml 37% Green	00817441022924
008-070SF	Silica-Free Etch Gel Syringe 4 g w/5 tips 37% Blue	00817441023020
008-071SF	Silica-Free Etch Gel Syringe 4 g w/5 tips 37% Green	00817441023044
008-072SF	Silica-Free Etch Gel Syringe 1.2 ml w/3 tips 37% Blue	00817441022986
008-073SF	Silica-Free Etch Gel Syringe 1.2 ml w/3 tips 37% Green	00817441023006
008-042SF	Silica-Free Etch Gel Bottle (Oval) 7.5 ml 37% Blue	00817441023105
008-043SF	Silica-Free Etch Gel Bottle (Oval) 7.5 ml 37% Green	00817441023129
	<b>Prime-Dent Etchant Liquid</b>	
008-040	Etch Liquid Bottle 8 oz. 37% Blue	00817441023136
008-041	Etch Liquid Bottle 8 oz. 37% Green	00817441023143
008-044	Etch Liquid Bottle (Oval) 7.5 ml 37% Blue	00817441023150
008-045	Etch Liquid Bottle (Oval) 7.5 ml 37% Green	00817441023167
	<b>Prime-Dent Porcelain Etchant</b>	
008-050	Porcelain Etch Gel Syringe 3.5 g w/Tips	00817441022801
008-052	Porcelain Etch Gel 4 Syringe Kit (4 x 1.2ml)	00817441028827

**Type of Product: Orthodontic Adhesives**

**Technical File No.: TF09**

Class: IIa, Rule 8

Product Names: Prime-Dent Paste/Paste Orthodontic Adhesive

Prime-Dent Dual Cure Glass Ionomer Band Cement

Prime-Dent Light Cure Glass Ionomer Band Cement

Prime-Dent Light Cure Orthodontic Adhesive

Prime-Dent One-Step Orthodontic Adhesive

Prime-Dent Megaset

ITEM NUMBER	DESCRIPTION	UDI
	<b>Prime-Dent Paste/Paste Orthodontic Adhesive</b>	
013-020	Paste/Paste Orthodontic Adhesive Kit 15/15gm in Jars	00817441026205
013-021	Paste/Paste Orthodontic Adhesive Kit 5/5gm in Jars	00817441026212
013-022	Paste/Paste Orthodontic Adhesive Kit 5/5gm Syringes	00817441026229
013-041	Paste/Paste Orthodontic Base Paste 15gm Jar	00817441026236
013-042	Paste/Paste Orthodontic Catalyst Paste 15gm Jar	00817441026243
013-044	Paste/Paste Orthodontic Base Paste 5gm Syringe	00817441026250
013-045	Paste/Paste Orthodontic Catalyst Paste 5gm Syringe	00817441026267
013-046	Paste/Paste Orthodontic Base Paste 5gm Jar	00817441026274
013-047	Paste/Paste Orthodontic Catalyst Paste 5gm Jar	00817441026281
	<b>Prime-Dent Dual Cure Glass Ionomer Band Cement</b>	
015-020	Dual Cure G. I. Band Cement w/Fluoride Releasing Kit 8-5g Syrs. (Natural or	00817441026298



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	Blue)	
015-021	Dual Cure G. I. Band Cement w/Fluoride Releasing Kit 2-5g Syrs. (Natural or Blue)	00817441026304
015-027	Automix Dual Cure G.I. Band Cement w/Fluoride Releasing Kit 4-10gm Syrs. (A2)	00817441026311
015-028	Automix Dual Cure G.I. Band Cement w/Fluoride Releasing Kit 1-10gm Syrs. (A2)	00817441026328
015-060	Automix Dual Cure G.I. Band Cement w/Fluoride Releasing Kit 4-10gm Syrs. (Blue)	00817441026335
015-061	Automix Dual Cure G.I. Band Cement w/Fluoride Releasing Kit 1-10gm Syrs. (Blue)	00817441026342
015-031	Dual Cure G. I. Band Cement w/Fluoride Releasing Base Paste 5g Syr.	00817441026359
015-036	Dual Cure G. I. Band Cement w/Fluoride Releasing Catalyst. Paste Refill 5g Syr.	00817441026366
015-038	Automix Dual Cure G. I Band Cement w/Fluoride Releasing Paste 10 g Syringe Refill (A2)	00817441026373
015-062	Automix Dual Cure G.I. Band Cement w/Fluoride Releasing Paste 10g Syringe Refill (Blue)	00817441026380
003-046	PDM Brown Mixing Tips & 25 Intra Oral Tips 25&25/Bag	00817441026120
003-047	Sulzer Mixpax Brown Mixing Tips & 25 Fine Intra Oral Tips 25&25/Bag	00817441026137
	<b>Prime-Dent Light Cure Glass Ionomer Band Cement</b>	
013-030	VLC Band Cement 4 x 5gm Syringes Natural Tint	00817441026397
013-031	VLC Band Cement 4 x 5 gm Syringes Blue Tint	00817441026403
015-032	VLC Orthodontic Band Cement 2 x 5 gm Syringes (natural)	00817441026410
015-033	VLC Orthodontic Band Cement 2 x 5 gm Syringes (blue)	00817441026427
015-034	VLC Orthodontic Band Cement 1 - 5 gm Syringe Natural Tint	00817441026434
015-035	VLC Orthodontic Band Cement 1 - 5 gm Syringe Blue Tint	00817441026441
	<b>Prime-Dent Light Cure Orthodontic Adhesive</b>	
012-020	VLC Orthodontic Adhesive Kit 4-5 g Syringes	00817441023778
012-021	VLC Orthodontic Adhesive Kit 1-5 g Syringe	00817441023792
012-022	VLC Orthodontic Adhesive Clamshell Kit 1-5 g Syringe	00817441023792
012-023	VLC Orthodontic Adhesive Kit [.35 g x 40 compules]	00817441023808
012-024	VLC Orthodontic Adhesive Clamshell Kit 2-5 g Syringes	00817441023815
012-031	VLC Orthodontic Adhesive Paste 5 g Syringe	00817441023839
012-032	VLC Orthodontic Adhesive Bonding Resin 7 ml Bottle	00817441023839
012-033	VLC Orthodontic Adhesive Bonding Resin 3 ml Bottle	00817441023846
	<b>Prime-Dent One-Step Orthodontic Adhesive</b>	
011-016	One-Step Orthodontic Adhesive Kit in Compules [.35 g x 40 compules]	00817441026458
011-018	One-Step Orthodontic Adhesive Kit 5gm Jar	00817441026465
011-019	One-Step Orthodontic Adhesive Kit 1-5gm Syringes	00817441026472
011-021	One-Step Orthodontic Adhesive Kit 4-5 g Syringes	00817441026489
011-022	One-Step Orthodontic Adhesive Clamshell Kit 1 -5 g Syringe	00817441026496
011-027	One-Step orthodontic Adhesive Clamshell Kit 2-5 g Syringes	00817441026502
011-202	One-Step Orthodontic Adhesive Kit 15gm Jar	00817441026519
011-031	One-Step Orthodontic Adhesive Paste 5 g Refill Syringe	00817441026526
011-032	One-Step Orthodontic Adhesive Paste 15 g Jar	00817441026533
011-033	One-Step Orthodontic Adhesive Paste 5 g Jar	00817441026540
011-034	One-Step Orthodontic Primer 12 ml Bottle	00817441026557
011-035	One-Step Orthodontic Primer 5 ml Bottle	00817441026564
	<b>Prime-Dent Megaset</b>	
1111-0001	Megaset Orthodontic 1 Syringe Set	00817441026571
1111-0002	Megaset Orthodontic 3 Syringe Set	00817441026588

**Type of Product: Dental Pit and Fissure Sealants and Liners**





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**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

ITEM NUMBER	DESCRIPTION	UDI
	<b>Prime-Dent Light Cure Pit and Fissure Sealant</b>	
007-020	VLC Pit and Fissure Sealant Kit (clear) (2-3 ml Sealant, 7.5 ml etch)	00817441023211
007-021	VLC Pit and Fissure Sealant Kit (opaque) (2-3 ml sealant, 7.5 ml etch)	00817441023228
007-022	VLC Pit and Fissure Sealant Kit (clear) (3-1.5 g Syrs., 1.2 ml etch gel syr. w/tips)	00817441023235
007-023	VLC Pit and Fissure Sealant Kit (opaque) (3-1.5 g Syrs., 1.2 ml etch gel syr. w/tips)	00817441023242
007-024	VLC Pit and Fissure Sealant Bottle 3 ml Opaque	00817441023259
007-025	VLC Pit and Fissure Sealant Syringe 1.5 g Opaque	00817441023266
007-026	VLC Pit and Fissure Sealant Bottle 3 ml Clear	00817441023273
007-027	VLC Pit and Fissure Sealant Syringe 1.5 g Clear	00817441023280
	<b>Prime-Dent Chemical Cure Pit and Fissure Sealant</b>	
007-010	Chemical Cure Pit and Fissure Sealant Kit (clear) (3ml base, 3ml catalyst, 7.5ml etch)	00817441023297
007-011	Chemical Cure Pit and Fissure Sealant Kit (opaque) (3ml base, 3ml catalyst, 7.5ml etch)	00817441023303
007-010	Chemical Cure Pit and Fissure Sealant Kit (clear) (3ml base, 3ml catalyst, 7.5ml etch)	00817441023310
007-011	Chemical Cure Pit and Fissure Sealant Kit (opaque) (3ml base, 3ml catalyst, 7.5ml etch)	00817441023327
007-014	Chemical Cure Pit and Fissure Sealant Bottle 3 ml Base	00817441023334
	<b>Prime-Blend Ultra</b>	
200-001	Prime Blend Ultra Kit 4 x 2g Syringes (Calcium Hydroxide)	00817441022726
200-000	Prime Blend Ultra 2 g Syringe Refill (Calcium Hydroxide)	00817441022733
200-002	Prime Blend Ultra 5 g Syringe Refill (Calcium Hydroxide)	00817441022740

**Type of Product: Dental Desensitizer**

**Technical File No.: TF11**

Class: IIa, Rule 6

Product Names: Prime-Dent Hema Desensitizer

ITEM NUMBER	DESCRIPTION	UDI
	<b>Prime-Dent Hema Desensitizer</b>	
018-011	Hema Desensitizer 7ml Bottle	00817441022757
018-030	Hema Desensitizer 4-1.2ml Syringe Kit	00817441022764
018-031	Hema Desensitizer 1.2 ml Syringe Refill	00817441022771

**Type of Product: Dental Root Canal Cleaning and Lubricating Gel**

**Technical File No.: TF12**

Class: IIa, Rule 6



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Product Names: RC-Cream

ITEM NUMBER	DESCRIPTION	UDI
	<b>RC-Cream</b>	
022-050	RC-Cream Kit (2 - 9 g syringes)	00817441023372
022-054	RC-Cream Kit (2 - 3 g syringes)	00817441023389
022-052	RC-Cream 9 g Syringe Refill	00817441023396
022-053	RC-Cream 5 g Syringe Refill	00817441023402
022-055	RC-Cream 3 g Syringe Refill	00817441023419

**Type of Product: Dental Temporary Crown and Bridge Materials**

**Technical File No.: TF13**

Class: IIa, Rule 5

Product Names: Prime-Crown

ITEM NUMBER	DESCRIPTION	UDI
	<b>Prime-Crown</b>	
100-103A1	Prime-Crown 90 g Kit [Shade: A1]	00817441022269
100-103A2	Prime-Crown 90 g Kit [Shade: A2]	00817441022276
100-103A3	Prime-Crown 90 g Kit [Shade: A3]	00817441022283
100-103A3.5	Prime-Crown 90 g Kit [Shade: A3.5]	00817441022290
100-103B1	Prime-Crown 90 g Kit [Shade: B1]	00817441022306
100-103B2	Prime-Crown 90 g Kit [Shade: B2]	00817441022313
100-104A1	Prime-Crown 90 g Refill [Shade: A1]	00817441022320
100-104A2	Prime-Crown 90 g Refill [Shade: A2]	00817441022337
100-104A3	Prime-Crown 90 g Refill [Shade: A3]	00817441022344
100-104A3.5	Prime-Crown 90 g Refill [Shade: A3.5]	00817441022351
100-104B1	Prime-Crown 90 g Refill [Shade: B1]	00817441022368
100-104B2	Prime-Crown 90 g Refill [Shade: B2]	00817441022375

**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

Prime-Dent Silane Bond Enhancer

Prime-Dent Porcelain Repair Kit

ITEM NUMBER	DESCRIPTION	UDI
	<b>Prime-Dent Metal Bond Enhancer</b>	
016-021	Metal Conditioner 10cc Bottle	00817441023518
	<b>Prime-Dent Plastic Bond Enhancer</b>	
016-020	Plastic Bond Enhancer 10cc Bottle	00817441023525



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	<b>Prime-Dent Porcelain Bond Enhancer</b>	
016-020	Porcelain Bond Enhancer 10cc Bottle	00817441023501
	<b>Prime-Dent Silane Bond Enhancer</b>	
008-SBE	Silane Bond Enhancer 4 Syringe Kit	00817441023853
	<b>Prime-Dent Porcelain Repair Kit</b>	
008-PRK	Prime-Dent Porcelain Repair Kit (Dental Dam, Etchant, Silane, Drying Agent)	00817441023860

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