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Declaration of Conformity

We, **MEDENTAL INTERNATIONAL INC (CONAMCO S.A. DE C.V.)**, located in **José Ma. Bustillos No. 28-Bis**, Col. Algarin, Deleg. Cuauhtemoc Ciudad de Mexico., C.P. 06880 México, declare that the following medical Device Meets the requirements of Medical Device 93/42/EEC, Annex V, amended by Council Directives 93/42/EEC, LVFS 2003:11 relating to medical devices

Under the supervision of the notified body number 0413, Intertek Semko AB, Certification Services, Box 1103, SE-164 22 Kista, Sweden.

Product:	Presentation:	Class:	MDD (Product List)	Code Proclinic
Medental Dentin / Enamel Bonding (Adhesivo Dentinario) Bestdent Reference: 60072	5 mL	II A	OPT558	OPT914
Medental Zinc Phosphate Cement (Cemento Fosfato de Zinc) Bestdent Reference: 20494	32 g + 15 mL	II A	OPT451	OPT1098
Medental Zinc Phosphate Cement (Cemento Fosfato de Zinc) Proclinic Reference: 35218	80 g + 55 mL	II A	OPT819	OPT1095
Medental Glass Ionomer Cement Type 1 (Cemento Ionómero T1) Proclinic Reference: 30501	20 g + 15 mL	II A	OPT391	OPT1052
Medental Glass Ionomer Cement Type 1 (Cemento Ionómero T1) Bestdent Reference: 30502	20 g + 15 mL	II A	OPT391	OPT1049
Medental Temporary Paste (Cemento Provisional) Bestdent Reference: 01551	38 g	II A	TC	OPT1099
Medental ZOE Cement Type III (Cemento ZOE Tipo III) Bestdent Reference: 30500	38 g + 14 mL	II A	OPT667	OPT1046
Medental Etchant (Grabador de Esmalte) Bestdent Reference: 60085	12 g	II A	OPT694	OPT935
Medental Flowable Composite Light Cure A1 (Composite Fluído A1) Bestdent Reference: 60166	2 g	II A	OPT614	OPT1241
Medental Flowable Composite Light Cure A2 (Composite Fluído A2) Bestdent Reference: 60073	2 g	II A	OPT615	OPT915

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Medental Flowable Composite Light Cure A3 (Composite Fluido A3) Bestdent Reference: 60074	2 g	II A	OPT616	OPT916
Medental Flowable Composite Light Cure A3.5 (Composite Fluido A3.5) Bestdent Reference: 60075	2 g	II A	OPT851	OPT917
Medental Flowable Composite Light Cure OA3 (Composite Fluido OA3) Bestdent Reference: 74087	2 g	II A	OPT616	OPT1307
Medental Flowable Composite Light Cure A4 (Composite Fluido A4) Bestdent Reference: 74088	2 g	II A	OPT1300	OPT1308
Medental Flowable Composite Light Cure B2 (Composite Fluido B2) Bestdent Reference: 60076	2 g	II A	OPT1001	OPT918
Medental Flowable Composite Light Cure C2 (Composite Fluido C2) Bestdent Reference: 74089	2 g	II A	OPT1063	OPT1309
Medental Flowable Composite Bulk Fill (Composite Fluido Bulk Fill) Bestdent Reference: 60168	2 g	II A	OPT614	OPT741
Medental Flowable Composite Bulk Fill (Composite Fluido Bulk Fill) Bestdent Reference: 60169	20 tips	II A	OPT1278	OPT750
Medental Micro Hybrid Light Cure A1 (Composite Restaurativo A1) Bestdent Reference: 60077	4 g	II A	OPT437	OPT919
Medental Micro Hybrid Light Cure A2 (Composite Restaurativo A2) Bestdent Reference: 60078	4 g	II A	OPT135	OPT920
Medental Micro Hybrid Light Cure A3 (Composite Restaurativo A3) Bestdent Reference: 60079	4 g	II A	OPT133	OPT921
Medental Micro Hybrid Light Cure A3.5 (Composite Restaurativo A3.5) Bestdent Reference: 60080	4 g	II A	OPT134	OPT922
Medental Micro Hybrid Light Cure OA3 (Composite Restaurativo OA3) Bestdent Reference: 74086	4 g	II A	OPT133	OPT1306

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Medental Micro Hybrid Light Cure A4 (Composite Restaurativo A4) Bestdent Reference: 60167	4 g	II A	OPT810	OPT1242
Medental Micro Hybrid Light Cure B2 (Composite Restaurativo B2) Bestdent Reference: 60081	4 g	II A	OPT521	OPT923
Medental Micro Hybrid Light Cure C2 (Composite Restaurativo C2) Bestdent Reference: 60082	4 g	II A	OPT575	OPT924
Medental Micro Hybrid Light Cure INCISAL (Composite Restaurativo INCISAL) Bestdent Reference: 60083	4 g	II A	OPT522	OPT925
Medental Microhybrid Light Cure Kit (Estuche Composite Restaurativo) Bestdent Reference: 60084	7 x 4 g	II A	OPT592	OPT936

Within these requirements we have prepared the required technical documentation including EC Certificate 41377502-01 CE Initial Certification date 19 May 2010, Issued 19 May 2020, Expiring 26 May 2024, ISO 13485:2016 Semko Certification Services. We have appointed Ivonne Richaud, c/Roger de Flor 297, 2º, 3a C.P. 08025 Barcelona, Barcelona España Tel. 34 93 458 55 53, to act as our authorized representative in the European Community. Compliance to standards:

- ISO 13485:2016
- EC 93/42/EEC Annex V
- EN1441

Full Name: Gerard Kaim

Position: President



Date: May 25, 2020