



EC DECLARATION OF CONFORMITY
According to Annex V and Annex VII of MDD 93/42/EEC

TF32 27 August 2009
GMDN 35870

GC EUROPE N.V.
Research Park
Interleuvenlaan 33
B-3001 Leuven
Belgium

We ensure and declare under our sole responsibility that the product :

GRADIA

to which this declaration relates is in conformity with the following standards or other normative documents :

**EN ISO 13485:2016 Medical Devices - Quality Management Systems-
Requirements for Regulatory Purposes**

ISO 10477:2020 - Dentistry - Polymer based crown and bridge materials

and meets the provisions of Council Directive 93/42/EEC concerning Medical Devices which apply to it, and is manufactured in accordance with the technical documentation.

This product is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n° 2797).

Leuven,17/05/2021.....
Date

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Mario Minale
Head of Regulatory Affairs
On behalf of GC EUROPE N.V.





LIST OF PRODUCTS

Article code WEP	Article code EEP	New Article code WEP	New Article code EEP	Description
001493	005217	10000225	10001129	GC GRADIA, Cervical Translucent, 2.9ml, CT-2
001494	005218	10000226	10001130	GC GRADIA, Cervical Translucent, 2.9ml, CT-3
001495	005219	10000227	10001131	GC GRADIA, Cervical Translucent, 2.9ml, CT-4
001464	005188	10000196	10001100	GC GRADIA, Dentin, 2.9ml, D-A1
001465	005189	10000197	10001101	GC GRADIA, Dentin, 2.9ml, D-A2
001466	005190	10000198	10001102	GC GRADIA, Dentin, 2.9ml, D-A3
001467	005191	10000199	10001103	GC GRADIA, Dentin, 2.9ml, D-A3.5
001468	005192	10000200	10001104	GC GRADIA, Dentin, 2.9ml, D-A4
001469	005193	10000201	10001105	GC GRADIA, Dentin, 2.9ml, D-B1
001470	005194	10000202	10001106	GC GRADIA, Dentin, 2.9ml, D-B2
001471	005195	10000203	10001107	GC GRADIA, Dentin, 2.9ml, D-B3
001472	005196	10000204	10001108	GC GRADIA, Dentin, 2.9ml, D-B4
001473	005197	10000205	10001109	GC GRADIA, Dentin, 2.9ml, D-C1
001474	005198	10000206	10001110	GC GRADIA, Dentin, 2.9ml, D-C2
001475	005199	10000207	10001111	GC GRADIA, Dentin, 2.9ml, D-C3
001476	005200	10000208	10001112	GC GRADIA, Dentin, 2.9ml, D-C4
001477	005201	10000209	10001113	GC GRADIA, Dentin, 2.9ml, D-D2
001478	005202	10000210	10001114	GC GRADIA, Dentin, 2.9ml, D-D3
001479	005203	10000211	10001115	GC GRADIA, Dentin, 2.9ml, D-D4
001480	005204	10000212	10001116	GC GRADIA, Enamel, 2.9ml, E-1
001481	005205	10000213	10001117	GC GRADIA, Enamel, 2.9ml, E-2
001482	005206	10000214	10001118	GC GRADIA, Enamel, 2.9ml, E-3
001483	005207	10000215	10001119	GC GRADIA, Enamel, 2.9ml, E-4
001487	005209	10000219	10001121	GC GRADIA, Enamel Intensive, 2.9ml, EI-1
001488	005210	10000220	10001122	GC GRADIA, Enamel Intensive, 2.9ml, EI-3
001851	005239	10000247	10001133	GC GRADIA, Enamel Intensive, 2.9ml, EI-5
001484	005208	10000216	10001120	GC GRADIA, Halo Enamel, 2.9ml, HE-1
001420	005142	10000163	10001067	GC GRADIA, Foundation Opaque, 2.4ml, (FO)
001421	005144	10000164	10001068	GC GRADIA, Opaque, 2.4ml, O-A1
001422	005145	10000165	10001069	GC GRADIA, Opaque, 2.4ml, O-A2
001423	005146	10000166	10001070	GC GRADIA, Opaque, 2.4ml, O-A3
001424	005147	10000167	10001071	GC GRADIA, Opaque, 2.4ml, O-A3.5
001425	005148	10000168	10001072	GC GRADIA, Opaque, 2.4ml, O-A4
001426	005149	10000169	10001073	GC GRADIA, Opaque, 2.4ml, O-B1
001427	005150	10000170	10001074	GC GRADIA, Opaque, 2.4ml, O-B2
001428	005151	10000171	10001075	GC GRADIA, Opaque, 2.4ml, O-B3
001429	005152	10000172	10001076	GC GRADIA, Opaque, 2.4ml, O-B4
001430	005153	10000173	10001077	GC GRADIA, Opaque, 2.4ml, O-C1
001431	005154	10000174	10001078	GC GRADIA, Opaque, 2.4ml, O-C2
001432	005155	10000175	10001079	GC GRADIA, Opaque, 2.4ml, O-C3
001433	005156	10000176	10001080	GC GRADIA, Opaque, 2.4ml, O-C4
001434	005157	10000177	10001081	GC GRADIA, Opaque, 2.4ml, O-D2





001435	005158	10000178	10001082	GC GRADIA, Opaque, 2.4ml, O-D3
001436	005159	10000179	10001083	GC GRADIA, Opaque, 2.4ml, O-D4
001438	005166	10000180	10001084	GC GRADIA, Opaqus Dentin, 2.9ml, OD-A1
001439	005167	10000181	10001085	GC GRADIA, Opaqus Dentin, 2.9ml, OD-A2
001440	005168	10000182	10001086	GC GRADIA, Opaqus Dentin, 2.9ml, OD-A3
001441	005169	10000183	10001087	GC GRADIA, Opaqus Dentin, 2.9ml, OD-A3.5
001442	005170	10000184	10001088	GC GRADIA, Opaqus Dentin, 2.9ml, OD-A4
001443	005171	10000185	10001089	GC GRADIA, Opaqus Dentin, 2.9ml, OD-B1
001444	005172	10000186	10001090	GC GRADIA, Opaqus Dentin, 2.9ml, OD-B2
001445	005173	10000187	10001091	GC GRADIA, Opaqus Dentin, 2.9ml, OD-B3
001446	005174	10000188	10001092	GC GRADIA, Opaqus Dentin, 2.9ml, OD-B4
001447	005175	10000189	10001093	GC GRADIA, Opaqus Dentin, 2.9ml, OD-C1
001448	005176	10000190	10001094	GC GRADIA, Opaqus Dentin, 2.9ml, OD-C2
001449	005177	10000191	10001095	GC GRADIA, Opaqus Dentin, 2.9ml, OD-C3
001450	005178	10000192	10001096	GC GRADIA, Opaqus Dentin, 2.9ml, OD-C4
001451	005179	10000193	10001097	GC GRADIA, Opaqus Dentin, 2.9ml, OD-D2
001452	005180	10000194	10001098	GC GRADIA, Opaqus Dentin, 2.9ml, OD-D3
001453	005181	10000195	10001099	GC GRADIA, Opaqus Dentin, 2.9ml, OD-D4
001485	005211	10000217	10001123	GC GRADIA, Pearl Enamel, 2.9ml, PE-1
001486	005212	10000218	10001124	GC GRADIA, Pearl Enamel, 2.9ml, PE-3
001489	005213	10000221	10001125	GC GRADIA, Translucent, 2.9ml, T-0
001490	005214	10000222	10001126	GC GRADIA, Translucent, 2.9ml, T-1
001491	005215	10000223	10001127	GC GRADIA, Translucent, 2.9ml, T-2
001492	005216	10000224	10001128	GC GRADIA, Translucent, 2.9ml, T-4
001852	005238	10000248	10001132	GC GRADIA, Translucent, 2.9ml, T-5
001908	001908	10000282	10000282	GC GRADIA GUM, Fiber, 0.4g Bottle, GF-71