



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

TF41 27 August 2009

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

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

GRADIA DIRECT
GRADIA DIRECT X

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

ISO 4049:2019 – Dentistry – Polymer based Restorative Materials

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

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

This family of products is Class IIa according to rule 8 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n°2797)

Leuven,27/01/2022.....
Date

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



LIST OF PRODUCTS

Article Code	New Article code	Description
001966	10000285	GRADIA Direct, Introductory Kit (35 Unitips) 35x Unitips 0.16ml in following shades: A2, A3, A3.5, AO3, CV, CT, P-A2, 1x shade guide
001967	10000286	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), A1
001968	10000287	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), A2
001969	10000288	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), A3
001970	10000289	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), A3.5
001971	10000290	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), AO3
001972	10000291	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), CV
001975	10000292	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), NT
001976	10000293	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), A4
001977	10000294	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), B2
001978	10000295	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), B3
001979	10000296	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), C3
001980	10000297	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), AO2
001981	10000298	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), AO4
001982	10000299	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), CVD
001983	10000300	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), BW
001984	10000301	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), CT
001985	10000302	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), WT
001986	10000303	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), GT
001987	10000304	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), CVT
001988	10000305	GRADIA Direct, Anterior, Syringe 2.7ml (4g), A1
001989	10000306	GRADIA Direct, Anterior, Syringe 2.7ml (4g), A2
001990	10000307	GRADIA Direct, Anterior, Syringe 2.7ml (4g), A3
001991	10000308	GRADIA Direct, Anterior, Syringe 2.7ml (4g), A3.5
001992	10000309	GRADIA Direct, Anterior, Syringe 2.7ml (4g), AO3
001993	10000310	GRADIA Direct, Anterior, Syringe 2.7ml (4g), CV
001996	10000311	GRADIA Direct, Anterior, Syringe 2.7ml (4g), NT
001997	10000312	GRADIA Direct, Posterior, Unitip 20x0.16ml (0.28g), P-A1
001998	10000313	GRADIA Direct, Posterior, Unitip 20x0.16ml (0.28g), P-A2
001999	10000314	GRADIA Direct, Posterior, Unitip 20x0.16ml (0.28g), P-A3
002000	10000315	GRADIA Direct, Posterior, Unitip 20x0.16ml (0.28g), P-A3.5
002002	10000316	GRADIA Direct, Posterior, Unitip 20x0.16ml (0.28g), P-NT
002003	10000317	GRADIA Direct, Posterior, Syringe 2.7ml (4.7g), P-A1
002004	10000318	GRADIA Direct, Posterior, Syringe 2.7ml (4.7g), P-A2
002005	10000319	GRADIA Direct, Posterior, Syringe 2.7ml (4.7g), P-A3
002006	10000320	GRADIA Direct, Posterior, Syringe 2.7ml (4.7g), P-A3.5
002008	10000321	GRADIA Direct, Posterior, Syringe 2.7ml (4.7g), P-NT
002039	10000326	GRADIA Direct, Introductory Kit (7 Syringes) 7x Syringes 2.7ml in following shades: A2, A3, A3.5, AO3, CV, CT, P-A2, 1x shade guide
002040	10000327	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), DT





002041	10000328	GRADIA Direct, Posterior, Unitip 20x0.16ml (0.28g), P-WT
002042	10000329	GRADIA Direct, Anterior, Syringe 2.7ml (4g), A4
002043	10000330	GRADIA Direct, Anterior, Syringe 2.7ml (4g), B2
002044	10000331	GRADIA Direct, Anterior, Syringe 2.7ml (4g), B3
002045	10000332	GRADIA Direct, Anterior, Syringe 2.7ml (4g), C3
002046	10000333	GRADIA Direct, Anterior, Syringe 2.7ml (4g), AO2
002047	10000334	GRADIA Direct, Anterior, Syringe 2.7ml (4g), AO4
002048	10000335	GRADIA Direct, Anterior, Syringe 2.7ml (4g), CVD
002049	10000336	GRADIA Direct, Anterior, Syringe 2.7ml (4g), CT
002050	10000337	GRADIA Direct, Anterior, Syringe 2.7ml (4g), BW
002051	10000338	GRADIA Direct, Anterior, Syringe 2.7ml (4g), WT
002052	10000339	GRADIA Direct, Anterior, Syringe 2.7ml (4g), GT
002053	10000340	GRADIA Direct, Anterior, Syringe 2.7ml (4g), DT
002054	10000341	GRADIA Direct, Anterior, Syringe 2.7ml (4g), CVT
002055	10000342	GRADIA Direct, Posterior, Syringe 2.7ml (4.7g), P-WT
002272	10000349	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), B1
002273	10000350	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), XBW
002274	10000351	GRADIA Direct, Anterior, Syringe 2.7ml (4g), B1
002275	10000352	GRADIA Direct, Anterior, Syringe 2.7ml (4g), XBW
003331	10000601	GRADIA Direct, Introductory Kit (35 Unitips) 35x Unitips 0.16ml in following shades: A2, A3, A3.5, AO3, CV, CT, P-A2, 1x shade guide
003333	10000603	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), A1
003334	10000604	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), A2
003335	10000605	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), A3
003336	10000606	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), A3.5
003337	10000607	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), AO3
003338	10000608	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), CV
003340	10000610	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), NT
003342	10000612	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), A4
003343	10000613	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), B2
003344	10000614	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), B3
003345	10000615	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), C3
003347	10000617	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), AO2
003348	10000618	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), AO4
003346	10000616	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), CVD
003341	10000611	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), BW
003350	10000620	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), CT
003349	10000619	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), WT
003351	10000621	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), GT
003352	10000622	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), CVT
003362	10000632	GRADIA Direct, Anterior, Syringe 2.7ml (4g), A1
003363	10000633	GRADIA Direct, Anterior, Syringe 2.7ml (4g), A2
003364	10000634	GRADIA Direct, Anterior, Syringe 2.7ml (4g), A3
003365	10000635	GRADIA Direct, Anterior, Syringe 2.7ml (4g), A3.5
003373	10000643	GRADIA Direct, Anterior, Syringe 2.7ml (4g), AO3
003370	10000640	GRADIA Direct, Anterior, Syringe 2.7ml (4g), CV
003378	10000648	GRADIA Direct, Anterior, Syringe 2.7ml (4g), NT
003355	10000625	GRADIA Direct, Posterior, Unitip 20x0.16ml (0.28g), P-A1





003356	10000626	GRADIA Direct, Posterior, Unitip 20x0.16ml (0.28g), P-A2
003357	10000627	GRADIA Direct, Posterior, Unitip 20x0.16ml (0.28g), P-A3
003358	10000628	GRADIA Direct, Posterior, Unitip 20x0.16ml (0.28g), P-A3.5
003360	10000630	GRADIA Direct, Posterior, Unitip 20x0.16ml (0.28g), P-NT
003422	10000667	GRADIA Direct, Posterior, Syringe 2.7ml (4.7g), P-A1
003423	10000668	GRADIA Direct, Posterior, Syringe 2.7ml (4.7g), P-A2
003424	10000669	GRADIA Direct, Posterior, Syringe 2.7ml (4.7g), P-A3
003425	10000670	GRADIA Direct, Posterior, Syringe 2.7ml (4.7g), P-A3.5
003427	10000672	GRADIA Direct, Posterior, Syringe 2.7ml (4.7g), P-NT
003332	10000602	GRADIA Direct, Introductory Kit (7 Syringes) 7x Syringes 2.7ml in following shades: A2, A3, A3.5, AO3, CV, CT, P-A2, 1x shade guide
003339	10000609	GRADIA Direct, Anterior, Unitip 20x0.16ml (0.24g), DT
003359	10000629	GRADIA Direct, Posterior, Unitip 20x0.16ml (0.28g), P-WT
003366	10000636	GRADIA Direct, Anterior, Syringe 2.7ml (4g), A4
003367	10000637	GRADIA Direct, Anterior, Syringe 2.7ml (4g), B2
003368	10000638	GRADIA Direct, Anterior, Syringe 2.7ml (4g), B3
003369	10000639	GRADIA Direct, Anterior, Syringe 2.7ml (4g), C3
003372	10000642	GRADIA Direct, Anterior, Syringe 2.7ml (4g), AO2
003374	10000644	GRADIA Direct, Anterior, Syringe 2.7ml (4g), AO4
003371	10000641	GRADIA Direct, Anterior, Syringe 2.7ml (4g), CVD
003377	10000647	GRADIA Direct, Anterior, Syringe 2.7ml (4g), CT
003361	10000631	GRADIA Direct, Anterior, Syringe 2.7ml (4g), BW
003375	10000645	GRADIA Direct, Anterior, Syringe 2.7ml (4g), WT
003379	10000649	GRADIA Direct, Anterior, Syringe 2.7ml (4g), GT
003376	10000646	GRADIA Direct, Anterior, Syringe 2.7ml (4g), DT
003380	10000650	GRADIA Direct, Anterior, Syringe 2.7ml (4g), CVT
003426	10000671	GRADIA Direct, Posterior, Syringe 2.7ml (4.7g), P-WT
003354	10000624	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), B1
003353	10000623	GRADIA Direct, Anterior, Unitip 10x0.16ml (0.24g), XBW
003388	10000652	GRADIA Direct, Anterior, Syringe 2.7ml (4g), B1
003387	10000651	GRADIA Direct, Anterior, Syringe 2.7ml (4g), XBW
002601	10000428	GRADIA Direct X, Syringe 2.7ml (5g), X-A1
002602	10000429	GRADIA Direct X, Syringe 2.7ml (5g), X-A2
002603	10000430	GRADIA Direct X, Syringe 2.7ml (5g), X-A3
002604	10000431	GRADIA Direct X, Syringe 2.7ml (5g), X-A3.5
002607	10000433	GRADIA Direct X, Syringe 2.7ml (5g), X-AO2
002605	10000432	GRADIA Direct X, Syringe 2.7ml (5g), X-WT
002596	10000427	GRADIA Direct X, Unitip 10x0.16ml (0.3g), X-AO2
002590	10000422	GRADIA Direct X, Unitip 20x0.16ml (0.3g), X-A1
002591	10000423	GRADIA Direct X, Unitip 20x0.16ml (0.3g), X-A2
002592	10000424	GRADIA Direct X, Unitip 20x0.16ml (0.3g), X-A3
002593	10000425	GRADIA Direct X, Unitip 20x0.16ml (0.3g), X-A3.5
002594	10000426	GRADIA Direct X, Unitip 20x0.16ml (0.3g), X-WT
003403	10000659	GRADIA Direct X, Syringe 2.7ml (5g), X-A1
003404	10000660	GRADIA Direct X, Syringe 2.7ml (5g), X-A2
003405	10000661	GRADIA Direct X, Syringe 2.7ml (5g), X-A3
003406	10000662	GRADIA Direct X, Syringe 2.7ml (5g), X-A3.5





003409	10000664	GRADIA Direct X, Syringe 2.7ml (5g), X-AO2
003407	10000663	GRADIA Direct X, Syringe 2.7ml (5g), X-WT
003396	10000658	GRADIA Direct X, Unitip 10x0.16ml (0.3g), X-AO2
003390	10000654	GRADIA Direct X, Unitip 20x0.16ml (0.3g), X-A1
003391	10000655	GRADIA Direct X, Unitip 20x0.16ml (0.3g), X-A2
003392	10000656	GRADIA Direct X, Unitip 20x0.16ml (0.3g), X-A3
003393	10000657	GRADIA Direct X, Unitip 20x0.16ml (0.3g), X-A3.5
003394	10006654	GRADIA Direct X, Unitip 20x0.16ml (0.3g), X-WT
890360	10003240	Gradia Direct Premium Kit EEP
901529	10004813	Gradia Direct Posterior MEA 1syr P-A3,5
901525	10004818	Gradia Direct Anterior MEA 1syr AO2
901524	10004819	Gradia Direct Anterior MEA 1syr A3,5
901523	10004821	Gradia Direct Anterior MEA 1syr A3
901522	10004822	Gradia Direct Anterior MEA 1syr A2
901521	10004868	Gradia Direct Anterior MEA 1syr A1
901527	10004909	Gradia Direct Posterior MEA 1syr P-A2
901526	10004910	Gradia Direct Posterior MEA 1syr P-A1
901528	10004911	Gradia Direct Posterior MEA 1syr P-A3