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

TF41 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 products:

GRADIA DIRECT
GRADIA DIRECT X

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

GC Company Standard AB-15-Q-301-348(9)

ISO 4049:2000 – Dentistry – Polymer based filling, restorative and luting materials

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 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n°0086)

Leuven, ...22/05/2018.....
Date

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

LIST OF PRODUCTS

Article code	Description
001966	Gradia Direct Unitip Introductory Kit
001967	Gradia Direct Unitip A1 20 pcs
001968	Gradia Direct Unitip A2 20 pcs
001969	Gradia Direct Unitip A3 20 pcs
001970	Gradia Direct Unitip A3.5 20 pcs
001971	Gradia Direct Unitip AO3 20 pcs
001972	Gradia Direct Unitip CV 20 pcs
001975	Gradia Direct Unitip NT 20 pcs
001976	Gradia Direct Unitip A4 10 pcs
001977	Gradia Direct Unitip B2 10 pcs
001978	Gradia Direct Unitip B3 10 pcs
001979	Gradia Direct Unitip C3 10 pcs
001980	Gradia Direct Unitip AO2 10 pcs
001981	Gradia Direct Unitip AO4 10 pcs
001982	Gradia Direct Unitip CVD 10 pcs
001983	Gradia Direct Unitip BW 10 pcs
001984	Gradia Direct Unitip CT 10 pcs
001985	Gradia Direct Unitip WT 10 pcs
001986	Gradia Direct Unitip GT 10 pcs
001987	Gradia Direct Unitip CVT 10 pcs
001988	Gradia Direct Syringe A1 1 pce
001989	Gradia Direct Syringe A2 1 pce
001990	Gradia Direct Syringe A3 1 pce
001991	Gradia Direct Syringe A3.5 1 pce
001992	Gradia Direct Syringe AO3 1 pce
001993	Gradia Direct Syringe CV 1 pce
001996	Gradia Direct Syringe NT 1 pce
001997	Gradia Direct Unitip P-A1 20 pcs
001998	Gradia Direct Unitip P-A2 20 pcs
001999	Gradia Direct Unitip P-A3 20 pcs
002000	Gradia Direct Unitip P-A3.5 20 pcs
002002	Gradia Direct Unitip P-NT 20 pcs
002003	Gradia Direct Syringe P-A1 1 pce
002004	Gradia Direct Syringe P-A2 1 pce
002005	Gradia Direct Syringe P-A3 1 pce
002006	Gradia Direct Syringe P-A3.5 1 pce
002008	Gradia Direct Syringe P-NT 1 pce
002039	Gradia Direct Syringe Introductory Kit
002040	Gradia Direct Unitip DT 20 pcs
002041	Gradia Direct Unitip P-WT 20 pcs
002042	Gradia Direct Syringe A4 1 pce
002043	Gradia Direct Syringe B2 1 pce
002044	Gradia Direct Syringe B3 1 pce

002045	Gradia Direct Syringe C3 1 pce
002046	Gradia Direct Syringe AO2 1 pce
002047	Gradia Direct Syringe AO4 1 pce
002048	Gradia Direct Syringe CVD 1 pce
002049	Gradia Direct Syringe CT 1 pce
002050	Gradia Direct Syringe BW 1 pce
002051	Gradia Direct Syringe WT 1 pce
002052	Gradia Direct Syringe GT 1 pce
002053	Gradia Direct Syringe DT 1 pce
002054	Gradia Direct Syringe CVT 1 pce
002055	Gradia Direct Syringe P-WT 1 pce
002234	Mixing pad 14B 5 pcs
002272	Gradia Direct Unitip B1 10 pcs
002273	Gradia Direct Unitip XBW 10 pcs
002274	Gradia Direct Syringe B1 pce
002275	Gradia Direct Syringe XBW 1 pce
002590	Gradia Direct X Unitip X-A1 20 pcs
002591	Gradia Direct X Unitip X-A2 20 pcs
002592	Gradia Direct X Unitip X-A3 20 pcs
002593	Gradia Direct X Unitip X-A3.5 20 pcs
002594	Gradia Direct X Unitip X-WT 20 pcs
002596	Gradia Direct X Unitip X-AO2 10 pcs
002601	Gradia Direct X Syringe X-A1 1 pce
002602	Gradia Direct X Syringe X-A2 1 pce
002603	Gradia Direct X Syringe X-A3 1 pce
002604	Gradia Direct X Syringe X-A3.5 1 pce
002605	Gradia Direct X Syringe X-WT 1 pce
002607	Gradia Direct X Syringe X-AO2 1 pce
003331	Gradia Direct Unitip Intro Kit EEP
003332	Gradia Direct Syringe Intro Kit EEP
003333	Gradia Direct Unitip A1 20 pcs EEP
003334	Gradia Direct Unitip A2 20 pcs EEP
003335	Gradia Direct Unitip A3 20 pcs EEP
003336	Gradia Direct Unitip A3.5 20 pcs EEP
003337	Gradia Direct Unitip AO3 20 pcs EEP
003338	Gradia Direct Unitip CV 20 pcs EEP
003339	Gradia Direct Unitip DT 20 pcs EEP
003340	Gradia Direct Unitip NT 20 pcs EEP
003341	Gradia Direct Unitip BW 10 pcs EEP
003342	Gradia Direct Unitip A4 10 pcs EEP
003343	Gradia Direct Unitip B2 10 pcs EEP
003344	Gradia Direct Unitip B3 10 pcs EEP
003345	Gradia Direct Unitip C3 10 pcs EEP
003346	Gradia Direct Unitip CVD 10 pcs EEP
003347	Gradia Direct Unitip AO2 10 pcs EEP
003348	Gradia Direct Unitip AO4 10 pcs EEP
003349	Gradia Direct Unitip WT 10 pcs EEP
003350	Gradia Direct Unitip CT 10 pcs EEP

003351	Gradia Direct Unitip GT 10 pcs EEP
003352	Gradia Direct Unitip CVT 10 pcs EEP
003353	Gradia Direct Unitip XBW 10 pcs EEP
003354	Gradia Direct Unitip B1 10 pcs EEP
003355	Gradia Direct Unitip P-A1 20 pcs EEP
003356	Gradia Direct Unitip P-A2 20 pcs EEP
003357	Gradia Direct Unitip P-A3 20 pcs EEP
003358	Gradia Direct Unitip P-A3.5 20 pcs EEP
003359	Gradia Direct Unitip P-WT 20 pcs EEP
003360	Gradia Direct Unitip P-NT 20 pcs EEP
003361	Gradia Direct Syringe BW 1 pce EEP
003362	Gradia Direct Syringe A1 1 pce EEP
003363	Gradia Direct Syringe A2 1 pce EEP
003364	Gradia Direct Syringe A3 1 pce EEP
003365	Gradia Direct Syringe A3.5 1 pce EEP
003366	Gradia Direct Syringe A4 1 pce EEP
003367	Gradia Direct Syringe B2 1 pce EEP
003368	Gradia Direct Syringe B3 1 pce EEP
003369	Gradia Direct Syringe C3 1 pce EEP
003370	Gradia Direct Syringe CV 1 pce EEP
003371	Gradia Direct Syringe CVD 1 pce EEP
003372	Gradia Direct Syringe AO2 1 pce EEP
003373	Gradia Direct Syringe AO3 1 pce EEP
003374	Gradia Direct Syringe AO4 1 pce EEP
003375	Gradia Direct Syringe WT 1 pce EEP
003376	Gradia Direct Syringe DT 1 pce EEP
003377	Gradia Direct Syringe CT 1 pce EEP
003378	Gradia Direct Syringe NT 1 pce EEP
003379	Gradia Direct Syringe GT 1 pce EEP
003380	Gradia Direct Syringe CVT 1 pce EEP
003387	Gradia Direct Syringe XBW 1 pce EEP
003388	Gradia Direct Syringe B1 pce EEP
003390	Gradia Direct X Unitip X-A1 20 pcs EEP
003391	Gradia Direct X Unitip X-A2 20 pcs EEP
003392	Gradia Direct X Unitip X-A3 20 pcs EEP
003393	Gradia Direct X Unitip X-A3.5 20 pcs EEP
003394	Gradia Direct X Unitip X-WT 20 pcs EE
003396	Gradia Direct X Unitip X-AO2 10 pcs EEP
003403	Gradia Direct X Syringe X-A1 1 pce EEP
003404	Gradia Direct X Syringe X-A2 1 pce EEP
003405	Gradia Direct X Syringe X-A3 1 pce EEP
003406	Gradia Direct X Syringe X-A3.5 1 pce EEP
003407	Gradia Direct X Syringe X-WT 1 pce EEP
003409	Gradia Direct X Syringe X-AO2 1 pce EEP
003422	Gradia Direct Syringe P-A1 1 pce EEP
003423	Gradia Direct Syringe P-A2 1 pce EEP
003424	Gradia Direct Syringe P-A3 1 pce EEP
003425	Gradia Direct Syringe P-A3.5 1 pce EEP

003426	Gradia Direct Syringe P-WT 1 pce EEP
003427	Gradia Direct Syringe P-NT 1 pce EEP
800176	Gradia Direct Syringe Complete Kit
890202	Gradia Direct Syr. & G-Bottle promo pack
890360	Gradia Direct Premium Kit EEP