

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

TF41 27 August 2009 GMDN 38764

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

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

GC GRADIA DIRECT GC GRADIA DIRECT X Light-Cured Composite Restorative

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,04/06/2014.....

Date

M. Aydin

Head Quality Assurance and

Regulatory Affairs

On behalf of GC EUROPE N.V.



GC Europe Head Office Interleuvenlaan 33 B-3001 Leuven