

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

TF48 06 Aug. 2009
GMDN 16704

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 Flo
GC GRADIA DIRECT LoFlo

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

ISO 4049:2000 – DENTISTRY – POLYMER BASED FILLING, RESTORATIVE and LUTING MATERIALS

ISO 1641:2004 MEDICAL DEVICES FOR DENTISTRY - 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 annex IX of the Council Directive.



Leuven, ..25/08/09.....
Date

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J. Van Bragt
Quality Systems Manager
On behalf of GC EUROPE N.V.