

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

TF4100 060425

GC EUROPE N.V. Research Park Interleuvenlaan 13 B-3001 Leuven Belgium

We ensure and declare under our sole responsibility that the product

## GRADIA DIRECT – Light Cured dental Restorative

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

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

ISO 1641:1996 - MEDICAL DEVICES FOR DENTISTRY - MATERIALS

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

This products is Class IIa according to annex IX of the Council Directive

2 6 APR. 2006

Date

Dr. P. Manouvriez

Compliance and Quality Systems Manager

On behalf of GC EUROPE N.V.