



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

TF49 19 April 2007

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

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

GC Tooth Mousse

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

EN ISO 13485:2012 Medical Devices - Quality Management Systems-
Requirements for Regulatory Purposes

GC Company standard AB-15-Q-301-352 (6)

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.

These products are Class I according to rule 5 of annex IX of the Council Directive.

Leuven, ...20/02/2015.....
Date

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M. Aydin
Head Quality Assurance and
Regulatory Affairs
On behalf of GC EUROPE N.V.



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