



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

TF75 4 Oct 2010  
GMDN 35876

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

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

**GC G-aenial Flo**

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

**EN ISO 13485:2016 Medical devices -- Quality management systems --  
Requirements for regulatory purposes**

**ISO 4049: 2009 Dentistry – Polymer-based filling, restorative and luting materials**

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

G-aenial Flo is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n°2797)

Leuven, .....17/05/2019.....  
Date

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



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