



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

TF 77 September 2010

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

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

G-aenial Bond

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 29022:2013 Dentistry – Adhesion – notched-edge shear bond strength test

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.

This product is Class IIa according to rule 8 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n°2797).

Leuven,09/03/2021.....
Date

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





LIST OF PRODUCTS

Article Code	New Article code	Description
011944	10001369	G-ænia Bond 3-bottle Pack 3x Bottle 5ml
011942	10001367	G-ænia Bond Kit, 5ml bottle
011947	10001371	G-ænia Bond, Bottle Refill, 5ml
011945	10001370	G-ænia Bond 3-bottle Pack 3x Bottle 5ml
011943	10001368	G-ænia Bond Kit, 5ml bottle
011948	10001372	G-ænia Bond, Bottle Refill, 5ml
900614	10003323	G-ænia Bond Promo Pack