



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

TF 77 September 2010
GMDN 34782

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 :

ISO/TS 11405:2015 – Dental materials - Testing of adhesion to tooth structure

Company Specifications 2CA-1201-3-10884

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 5 of annex IX of the Council Directive.

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

Leuven,16/04/2019.....
Date


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



LIST OF PRODUCTS

Article code	Description
011942	G-aenial Bond Kit, 5ml bottle
011944	G-aenial Bond 3-bottle Pack
011947	G-aenial Bond Refill
011943	G-aenial Bond 5ml Kit, EEP
011945	G-aenial Bond 3-bottle Pack, EEP
011948	G-aenial Bond 5ml Bottle Refill, EEP
890357	G-aenial Bond Sample 3 unidoses
900614	G-aenial Bond Promo Pack