



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

TF116 03 Nov 2014
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-Premio BOND

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

ISO 4049: 2019 Dentistry - Polymer-based restorative materials

**EN ISO 13485:2016 Medical Devices -Quality Management Systems-
Requirements for Regulatory Purposes**

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
012694	10001461	GC G-Premio BOND, Bottle Refill, 5ml
012688	10001458	GC G-Premio BOND, 3-Bottle Pack
012687	10001457	GC G-Premio BOND, Kit, 5ml
009552	10001349	GC G-Premio BOND DCA, Bottle Refill, 3ml
012694	10001461	GC G-Premio BOND, Bottle Refill, 5ml
009034	10001242	GC G-Premio BOND, Unit Dose, 50 pcs