EC DECLARATION OF CONFORMITY
According to Annex V and 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 :

EN ISO 13485:2012 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.

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

Notified Body: British Standards Institution (n° 0086).

Leuven, ...09/10/2018.....
Date

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

LIST OF PRODUCTS

Article code	Description
012687	GC G-Premio BOND, Kit, 5mL
012688	G-Premio BOND 3-bottle Pack
009034	G-Premio BOND Unit Dose 50 pce
012689	G-Premio BOND 5mL Kit EE
012690	G-Premio BOND 3-bottle Pack EE
009035	G-Premio BOND Unit Dose 50 pce EE
012694	G-Premio BOND 5mL Bottle Refill
012695	G-Premio BOND 5mL Bottle Refill EE
901021	G-Premio BOND sample pack
901466	PROMO G-Premio BOND + Essentia U syringe
901467	PROMO G-Premio BOND + Essentia U unitip

GC Europe Head Office
Interleuvenlaan 33
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