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

TF50 16 Nov. 2007
GMDN 34782

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

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

G-BOND
G-BOND Unit Dose

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

EN ISO 13485:2012 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

GC Company specification: AB-15-Q-301-357

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

These products are Class IIa according to rule 5 of annex IX of the Council Directive.

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

Leuven, ...14/02/2019.....
Date

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

LIST OF PRODUCTS

Article code	Description
002277	G-Bond, Starter Kit , Bottle
002302	G-Bond Starter Kit Unit Dose
003416	G-Bond, Starter Kit , Bottle EEP
003417	G-Bond Starter Kit Unit Dose EEP
890210	G-Bond Value Pack
900526	G-Bond Value Pack EEP