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

TF125 19 February 2016
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 DCA**

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 DCA** is Class IIa according to rule 5 of annex IX of the Council Directive.

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

Leuven, .....24/08/2018.....
Date

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

## LIST OF PRODUCTS

| Article code | Description |
|---|---|
| 009552 | G-Premio BOND DCA 3mL Refill |