



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

TF14 05 May 2006  
GMDN 36153

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

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

**CAVITY CONDITIONER**

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

**EN ISO 13485:2016 Medical devices - Quality management systems -  
Requirements for regulatory purposes**

**EN 1641:2009 Dentistry - Medical devices for dentistry - Materials**

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, .....17/05/2021.....  
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
000110	10000019	Cavity Conditioner 5,7ml