



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

TF 161  
GMDN 62477

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

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

**COMPOSITE PRIMER**

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**

**Company specification: EB-12-Q-301-776 (0)**

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
001530	10000237	Composite Primer, 3ml Liquid
004865	10001024	Composite Primer, 3ml Liquid