



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

TF148

29 September 2017

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

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

GC Modeling Liquid

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

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

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 8 of annex IX of the Council Directive.

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

Leuven, 09/03/2021.....
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
900743	10003387	GC Composite Modelling Kit 1x GC Modelling Liquid 6ml, 2x Gradia Brush Holder, 5x Gradia Brush Flat, 5x Gradia Brush Round, 1x Mixing pad
012243	10001380	GC Modelling Liquid, Refill 6ml
900744	10003388	GC Composite Modelling Kit 1x GC Modelling Liquid 6ml, 2x Gradia Brush Holder, 5x Gradia Brush Flat, 5x Gradia Brush Round, 1x Mixing pad
012244	10001381	GC Modelling Liquid, Refill 6ml