



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

TF14 08 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 :

DENTIN 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	EEP article code	New article code	New EEP article code	Description
000120	014382	10000027	10007492	Dentin Conditioner 25ml