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

TF15 08 May 2006
GMDN 46939

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

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

FREEGENOL TEMPORARY PACK

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
ISO 3107:2011	Dentistry - Zinc oxide/eugenol cements and zinc oxide/non-eugenol cements

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 5 of annex IX of the Council Directive.

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

Leuven, ...16/04/2019.....
Date

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

LIST OF PRODUCTS

Article code	Description
000087	Freegenol Temporary Pack
003440	Freegenol Temporary Pack EEP