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

TF147 09 March 2018
GMDN 35870

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

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

G-aenial Universal Injectable

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 4049:2009	Dentistry — Polymer-based restorative materials
1AB-1500-3-10674	Company specification

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°0086).

Leuven, ...10 April 2018.....
Date

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

LIST OF PRODUCTS

Article code WEP	Article code EEP	Description
901471	901487	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), XBW
901472	901488	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), BW
901473	901489	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), A1
901474	901490	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), A2
901475	901491	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), A3
901476	901492	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), A3.5
901477	901493	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), A4
901478	901494	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), B1
901479	901495	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), B2
901480	901496	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), CV
901481	901497	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), CVD
901482	901498	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), AO1
901483	901499	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), AO2
901484	901500	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), AO3
901485	901501	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), JE
901486	901502	G-ænial Universal Injectable, Syringe 1x1mL (1,7g), AE