



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 13485:2016 Medical devices -- Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012
Medical devices -- Application of risk management to medical devices
EN 1641:2009 Dentistry -- Medical devices for dentistry - Materials
EN ISO 10993-1:2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 7405:2008/Amd 1:2013 Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied (Part 1: General requirements)
EN 1041:2008 + A1:2013 Information supplied by the manufacturer of medical devices
ISO 4049:2009 Dentistry – Polymer-based restorative 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 5 of annex IX of the Council Directive.

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

Leuven, 01 Febr 2021.....

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





LIST OF PRODUCTS

Article code			Description
Syringe 1x1mL (1.7g)		Unitips 15x0.16mL (0.27g)	
WEP	EEP	WEP&EEP	
10003703	10003719	10006910	GC G-ænia Universal Injectable, XBW
10003704	10003720	10006911	GC G-ænia Universal Injectable, BW
10003705	10003721	10006896	GC G-ænia Universal Injectable, A1
10003706	10003722	10006897	GC G-ænia Universal Injectable, A2
10003707	10003723	10006898	GC G-ænia Universal Injectable, A3
10003708	10003724	10006899	GC G-ænia Universal Injectable, A3.5
10003709	10003725	10006900	GC G-ænia Universal Injectable, A4
10003710	10003726	10006901	GC G-ænia Universal Injectable, B1
10003711	10003727	10006902	GC G-ænia Universal Injectable, B2
10003712	10003728	10006903	GC G-ænia Universal Injectable, CV
10003713	10003729	10006904	GC G-ænia Universal Injectable, CVD
10003714	10003730	10006905	GC G-ænia Universal Injectable, AO1
10003715	10003731	10006906	GC G-ænia Universal Injectable, AO2
10003716	10003732	10006907	GC G-ænia Universal Injectable, AO3
10003717	10003733	10006908	GC G-ænia Universal Injectable, JE
10003718	10003734	10006909	GC G-ænia Universal Injectable, AE
901509	901509	/	GC G-ænia Universal Injectable + G-Premio Bond Kit
/	/	10006971	GC G-ænia Universal Injectable SAMPLE (unitips)