



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

TF152
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 A'CHORD

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**

ISO 4049:2019 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 8 of annex IX of the Council Directive.

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

Leuven, 24/03/2021

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



LIST OF PRODUCTS

Article code	Description
10006739	G-ænia A'CHORD syringe A1
10006740	G-ænia A'CHORD syringe A2
10006741	G-ænia A'CHORD syringe A3
10006742	G-ænia A'CHORD syringe A3.5
10006743	G-ænia A'CHORD syringe A4
10006744	G-ænia A'CHORD syringe A5
10006745	G-ænia A'CHORD syringe A6
10006746	G-ænia A'CHORD syringe BW
10006747	G-ænia A'CHORD syringe AO1
10006748	G-ænia A'CHORD syringe AO2
10006749	G-ænia A'CHORD syringe AO3
10006750	G-ænia A'CHORD syringe BOW
10006751	G-ænia A'CHORD syringe JE
10006752	G-ænia A'CHORD syringe AE
10006753	G-ænia A'CHORD unitip A1
10006754	G-ænia A'CHORD unitip A2
10006755	G-ænia A'CHORD unitip A3
10006756	G-ænia A'CHORD unitip A3.5
10006757	G-ænia A'CHORD unitip A4
10006758	G-ænia A'CHORD unitip A5
10006759	G-ænia A'CHORD unitip A6
10006760	G-ænia A'CHORD unitip BW
10006761	G-ænia A'CHORD unitip AO1
10006762	G-ænia A'CHORD unitip AO2
10006763	G-ænia A'CHORD unitip AO3
10006764	G-ænia A'CHORD unitip BOW
10006765	G-ænia A'CHORD unitip JE
10006766	G-ænia A'CHORD unitip AE
10006767	G-ænia A'CHORD LAYERING KIT syringe
10006768	G-ænia A'CHORD CORE KIT syringe
10006769	G-ænia A'CHORD Trial Kit A Syringe
10006770	G-ænia A'CHORD Trial Kit B Syringe
10006771	G-ænia A'CHORD BLEACH KIT
10006772	G-ænia A'CHORD LAYERING KIT unitip
10006773	G-ænia A'CHORD CORE KIT unitip
10006774	G-ænia A'CHORD Trial Kit A Unitip
10006775	G-ænia A'CHORD Trial Kit B Unitip
10006779	G-ænia A'CHORD syringe A1 EEP
10006780	G-ænia A'CHORD syringe A2 EEP
10006781	G-ænia A'CHORD syringe A3 EEP
10006782	G-ænia A'CHORD syringe A3.5 EEP
10006783	G-ænia A'CHORD syringe A4 EEP



10006784	G-ænial A'CHORD syringe A5 EEP
10006785	G-ænial A'CHORD syringe A6 EEP
10006786	G-ænial A'CHORD syringe BW EEP
10006787	G-ænial A'CHORD syringe AO1 EEP
10006788	G-ænial A'CHORD syringe AO2 EEP
10006789	G-ænial A'CHORD syringe AO3 EEP
10006790	G-ænial A'CHORD syringe BOW EEP
10006791	G-ænial A'CHORD syringe JE EEP
10006792	G-ænial A'CHORD syringe AE EEP
10006835	G-ænial A'CHORD LAYERING KIT syr EEP
10006836	G-ænial A'CHORD CORE KIT syr EEP
10006737	G-ænial A'CHORD Trial Kit A Syringe
10006738	G-ænial A'CHORD Trial Kit B Syringe
10007061	G-aenial A'CHORD Syringe + G2 BOND Universal Kit (2 X A2 + 2 X A3 + 1 X G2 BOND Universal)
10007062	G-aenial A'CHORD Unitip + G2 BOND Universal Kit - 2 X A2 (30 U) + 2 X A3 (30 U) + 1 X G2 BOND Universal
10006916	G-aenial A'CHORD Syringe + G-Premio BOND (2 X A2 + 2 X A3 + 1 X G-Premio BOND)
10006917	G-aenial A'CHORD Unitip + G-Premio BOND (2 X A2 + 2 X A3 + 1 X G-Premio BOND)