



EU DECLARATION OF CONFORMITY
According to Annex II and Annex III of Regulation (EU) 2017/745

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

SRN: BE-MF-000001608

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

Product Name	GC Tooth Mousse
Intended Purpose	Topical creme with bio-available calcium and phosphate
Classification according to Annex VIII of the Regulation (EU) 2017/745	Class I, Rule 5
Article List	According to the Attachment
Basic UDI-DI	++J022MD0041JY

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

and meets the provisions of Regulation (EU) 2017/745 concerning Medical Devices which apply to it, and is manufactured in accordance with the technical documentation.

Leuven, 10 October 2022
Date

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





LIST OF PRODUCTS

Basic UDI-DI	Article Code	New Article code	Description
++J022MD0041JY	462032	10001743	GC Tooth Mousse, 10-Pack, Assorted
++J022MD0041JY	463299	10001755	GC Tooth Mousse, 10-Pack, Assorted
++J022MD0041JY	890102	10003205	GC Tooth Mousse, Promotional 5-Pack
++J022MD0041JY	900467	10003275	GC Tooth Mousse, Promotional 5-Pack
++J022MD0041JY	462521	10001746	GC Tooth Mousse, 10-Pack, Melon
++J022MD0041JY	463302	10001758	GC Tooth Mousse, 10-Pack, Melon
++J022MD0041JY	462522	10001747	GC Tooth Mousse, 10-Pack, Mint
++J022MD0041JY	463303	10001759	GC Tooth Mousse, 10-Pack, Mint
++J022MD0041JY	462520	10001745	GC Tooth Mousse, 10-Pack, Strawberry
++J022MD0041JY	463301	10001757	GC Tooth Mousse, 10-Pack, Strawberry
++J022MD0041JY	462523	10001748	GC Tooth Mousse, 10-Pack, Tutti-Frutti
++J022MD0041JY	463304	10001760	GC Tooth Mousse, 10-Pack, Tutti-Frutti
++J022MD0041JY	462270	10001744	GC Tooth Mousse, 10-Pack, Vanilla
++J022MD0041JY	463300	10001756	GC Tooth Mousse, 10-Pack, Vanilla

