



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	Classification according to Annex VIII of the Regulation (EU) 2017/745	Article List	Basic UDI-DI
GC MI Paste Plus	Class I, Rule 5	According to the Attachment	++J022MD0011JP

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, 17 May 2021
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
++J022MD0011JP	462614	10001749	GC MI Paste Plus, 10-Pack, Assorted
++J022MD0011JP	900441	10003270	GC MI Paste Plus, Promotional 5-Pack
++J022MD0011JP	462887	10001752	GC MI Paste Plus, 10-Pack, Melon
++J022MD0011JP	462621	10001750	GC MI Paste Plus, 10-Pack, Mint
++J022MD0011JP	462886	10001751	GC MI Paste Plus, 10-Pack, Strawberry
++J022MD0011JP	462889	10001754	GC MI Paste Plus, 10-Pack, Tutti Frutti
++J022MD0011JP	462888	10001753	GC MI Paste Plus, 10-Pack, Vanilla
++J022MD0011JP	463310	10001761	GC MI Paste Plus, 10-Pack, Assorted
++J022MD0011JP	900466	10003274	GC MI Paste Plus, Promotional 5-Pack
++J022MD0011JP	463313	10001764	GC MI Paste Plus, 10-Pack, Melon
++J022MD0011JP	463311	10001762	GC MI Paste Plus, 10-Pack, Mint
++J022MD0011JP	463312	10001763	GC MI Paste Plus, 10-Pack, Strawberry
++J022MD0011JP	463315	10001766	GC MI Paste Plus, 10-Pack, Tutti Frutti
++J022MD0011JP	463314	10001765	GC MI Paste Plus, 10-Pack, Vanilla