



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 Dry Mouth Gel	Class I, Rule 5	According to the Attachment	++J022MD0014JV

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.....13/05/2021...
Date

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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
++J022MD0014JV	003438	10000673	GC Dry Mouth Gel, 10-Pack, Assorted
	004617	10000913	GC Dry Mouth Gel, 10-Pack, Raspberry
	003222	10000517	GC Dry Mouth Gel, 10-Pack, Assorted
	004618	10000914	GC Dry Mouth Gel, 10-Pack, Raspberry