



**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 :

|                                                                               |                             |
|-------------------------------------------------------------------------------|-----------------------------|
| <b>Product Name</b>                                                           | GC MI Paste Plus            |
| <b>Intended Purpose</b>                                                       | Topical creme               |
| <b>Classification according to Annex VIII of the Regulation (EU) 2017/745</b> | Class I, Rule 5             |
| <b>Article List</b>                                                           | According to the Attachment |
| <b>Basic UDI-DI</b>                                                           | ++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, 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                             |
|----------------|--------------|------------------|-----------------------------------------|
| ++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      |