



**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
DIAPOLISHER PASTE	Class I, Rule 5	According to the Attachment	++J022MD0021JS

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

  
.....  
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
++J022MD0021JS	004415	10000892	GC DIAPOLISHER PASTE