



**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>	<b>Classification according to Annex VIII of the Regulation (EU) 2017/745</b>	<b>Article List</b>	<b>Basic UDI-DI</b>
StickREFIX L	Class I, Rule 5	According to the Attachment	++J022MD0025K2

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, 14 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
++J022MD0025K2	900824	10003409	GC StickREFIX L
++J022MD0025K2	900843	10003428	GC StickREFIX L