



**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>
GC TISSUE CONDITIONER	Class I, Rule 5	According to the Attachment	++J022MD0013JT
GC TISSUE CONDITIONER COATING AGENT	Class I, Rule 5	According to the Attachment	++J022MD0057KF

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, ...11/05/2021...  
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
++J022MD0013JT	002892	10000493	GC TISSUE CONDITIONER, Liquid 101ml (90g)
++J022MD0057KF	002893	10000494	GC TISSUE CONDITIONER, Coating 15ml (12g)
++J022MD0013JT	002894	10000495	GC TISSUE CONDITIONER, 1-1 Pack, Live Pink
++J022MD0013JT	002895	10000496	GC TISSUE CONDITIONER, 1-1 Pack, White
++J022MD0013JT	002896	10000497	GC TISSUE CONDITIONER, 90g Powder, White
++J022MD0013JT	002897	10000498	GC TISSUE CONDITIONER, 90g Powder, Live Pink
++J022MD0013JT	003455	10000690	GC TISSUE CONDITIONER, 1-1 Pack, Live Pink
++J022MD0013JT	003456	10000691	GC TISSUE CONDITIONER, 1-1 Pack, White
++J022MD0013JT	003457	10000692	GC TISSUE CONDITIONER, 90g Powder, Live Pink
++J022MD0013JT	003458	10000693	GC TISSUE CONDITIONER, 90g Powder, White
++J022MD0013JT	003459	10000694	GC TISSUE CONDITIONER, Liquid 101ml (90g)
++J022MD0057KF	003460	10000695	GC TISSUE CONDITIONER, Coating 15ml (12g)

