



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	GC TISSUE CONDITIONER	GC TISSUE CONDITIONER COATING AGENT
Intended Purpose	Tissue conditioning and relining material	Coating agent
Classification according to Annex VIII of the Regulation (EU) 2017/745	Class I, Rule 5	Class I, Rule 5
Article List	According to the Attachment	According to the Attachment
Basic UDI-DI	++J022MD0013JT	++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, ...10/10/2022...
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
++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)

