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 products :

Product Name	GC Mixing, Dispensing and Elongation Tips
Intended Purpose	Mixing and dispensing of dental materials
Classification according to Annex VIII of the Regulation (EU) 2017/745	Class I, Rule V
Article List	According to the Attachment
Basic UDI-DI	++J022MD0048KE

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
++J022MD0048KE	001926	10000283	GC Dispensing Tips Needle Type (Metal), 20pcs
++J022MD0048KE	001927	10000284	GC Dispensing Tips Plastic Type, 20pcs
++J022MD0048KE	004634	10000930	GC Dispensing Tip III Plastic, 30pcs
++J022MD0048KE	004635	10000931	Dispensing Tip III Needle, 30pcs
++J022MD0048KE	012954	10004917	GC Push and Click Tip Regular
++J022MD0048KE	012955	10004929	GC Push and Click Tip Endo
++J022MD0048KE	150004	10001538	GC Dynamic Mixing Tips, 370ml, 50pcs
++J022MD0048KE	800100	10001800	GC Mixing Tips II, 60xS (Pink)
++J022MD0048KE	800101	10001801	GC Mixing Tips II, 60xLL (Purple)
++J022MD0048KE	800119	10001805	GC Intra-Oral Tips, 100 pc.
++J022MD0048KE	890130	10003208	GC Mixing Tips II, 60xSS (Yellow)
++J022MD0048KE	900114	10003262	GC Universal Mixing Tips II Size L (Green/blue)
++J022MD0048KE	900483	10003283	GC Intra-Oral Tips, 100 pc., Yellow
++J022MD0048KE	900495	10003289	GC Automix Tip for Endo, 10pcs
++J022MD0048KE	900668	10003335	GC Automix Tip Regular, 10pcs
++J022MD0048KE	900902	10003464	GC FujiCEM 2 Mixing Tips SL, Refill Pack, 20pcs (only compatible with FujiCEM 2 SL cartridge)
++J022MD0048KE	900903	10003465	GC FujiCEM 2 Mixing Tips SL for Endo, Refill Pack (10pcs) (only compatible with FujiCEM 2 SL cartridge)
++J022MD0048KE	900915	10003470	FujiCem 2 SL Bulk Mixing Tips
++J022MD0048KE	901133	10003642	GC GRADIA PLUS Dispensing Tip Wide Plastic Type & Light Protective Cover, 5pcs
++J022MD0048KE	901134	10003643	GC GRADIA PLUS Dispensing Tip Needle Type Small & Light Protective Cover, 5pcs
++J022MD0048KE	901135	10003644	GC GRADIA PLUS Dispensing Tip Needle Type & Light Protective
++J022MD0048KE	901136	10003645	GRADIA PLUS Mixotip, 10pcs
++J022MD0048KE	901503	10003735	GC Dispensing tips long needle, 30 pcs.
++J022MD0048KE	901537	10003754	Mixing Tips Type II SSS
++J022MD0048KE	004414	10000891	GC Capsule Elongation tip, 50 pcs
++J022MD0048KE	952227	10006625	GC Fuji ORTHO LC, Paste Pak, Refill Mixing Tip, 20pcs
++J022MD0048KE	N/A	10007241	Push and click mixing tips 105 pcs