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
EPITEX	Class I, Rule 5	According to the Attachment	++J022MD0003JQ

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

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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
++J022MD0003JQ	000404	10000117	GC EPITEX, Starter Kit, Stand with Dispenser of each Grain
++J022MD0003JQ	000405	10000118	GC EPITEX, Refill, 10m, Coarse (blue)
++J022MD0003JQ	000406	10000119	GC EPITEX, Refill, 10m, Fine (grey)
++J022MD0003JQ	000407	10000120	GC EPITEX, Refill, 10m, Medium (green)
++J022MD0003JQ	000408	10000121	GC EPITEX, Refill, 10m, X-Fine (red)
++J022MD0003JQ	000409	10000122	GC EPITEX, Refill, 10m, Translucent Matrix