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
GC FujiCEM 2 Dispenser	Class I, Rule V	According to the Attachment	++J022MD0027K6

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, ...13/05/2021..
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 (S4/HANA Art.nr.)	Description
++J022MD0027K6	004647	70000009	GC FujiCEM 2, Dispenser