



EC DECLARATION OF CONFORMITY
According to Annex V and Annex VII of MDD 93/42/EEC

TF82 5 August 2011
GMDN 16704

GC EUROPE N.V.
Research Park
Interleuvenlaan 33
B-3001 Leuven
Belgium

We ensure and declare under our sole responsibility that the product :

GC Fuji TEMP LT

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**

EN 1641:2009 - Dentistry - Medical devices for dentistry - Materials

and meets the provisions of Council Directive 93/42/EEC concerning Medical Devices which apply to it, and is manufactured in accordance with the technical documentation.

This product is Class IIa according to rule 8 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n°2797).

Leuven,17/05/2021.....
Date

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Mario Minale
Head of Regulatory Affairs
On behalf of GC EUROPE N.V.



LIST OF PRODUCTS

Article Code	New Article Code	Description
004253	10000856	GC Fuji TEMP LT Content: 2x13.3g/7.2ml+ 1x Mixing pad N° 22
014384	10007514	GC Fuji TEMP LT EE Content: 2x13.3g/7.2ml+ 1x Mixing pad N° 22