



**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