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

TF145 24 March 2017
GMDN 45236

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

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

GC TEMP PRINT

to which this declaration relates is in conformity with the following standards or other normative documents :

EN ISO 13485:2012	*Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes*
EN ISO 14971:2012	*Medical devices -- Application of risk management to medical devices*
ISO 10993-5:2009	*Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity*
ISO 10477: 2004	*Dentistry – Polymer-based crown and bridge 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.

GC TEMP PRINT is Class IIa according to rule 8 of annex IX of the Council Directive.

Notified Body: Kiwa Cermet Italia S.p.A., Via Cadriano ,23 - 40057 Cadriano di Granarolo dell'Emilia (BO) (NB 0476).

Leuven, ...11/04/2019.....
Date

.....

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

LIST OF PRODUCTS

Article code	Description
901595	GC Temp PRINT Light, 500g
901596	GC Temp PRINT Medium, 500g