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

TF144 13 October 2016
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 :

TEMPSMART DC

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

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.

TEMPSMART DC is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n° 0086).

Leuven, ...20/09/2018.....
Date

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

LIST OF PRODUCTS

Art. Nr.	Description
012760	TEMPSMART DC 48mL cartridge A1
012761	TEMPSMART DC 48mL cartridge A2
012762	TEMPSMART DC 48mL cartridge A3
012763	TEMPSMART DC 48mL cartridge A3.5
012764	TEMPSMART DC 48mL cartridge B1
012765	TEMPSMART DC 48mL cartridge BW
012766	TEMPSMART DC 10mL syringe A1
012767	TEMPSMART DC 10mLsyringe A2
012768	TEMPSMART DC 10mL syringe A3
012769	TEMPSMART DC 10mL syringe B1
012770	TEMPSMART DC 48mL cartridge A1 EEP
012771	TEMPSMART DC 48mL cartridge A2 EEP
012772	TEMPSMART DC 48mL cartridge A3 EEP
012773	TEMPSMART DC 48mL cartridge A3.5 EEP
012774	TEMPSMART DC 48mL cartridge B1 EEP
012775	TEMPSMART DC 48mL cartridge BW EEP
012776	TEMPSMART DC 10mL syringe A1 EEP
012777	TEMPSMART DC 10mL syringe A2 EEP
012778	TEMPSMART DC 10mL syringe A3 EEP
012779	TEMPSMART DC 10mL syringe B1 EEP