



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 13485:2016 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 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
012760	10001463	TEMPSMART DC 48mL cartridge A1
012761	10001464	TEMPSMART DC 48mL cartridge A2
012762	10001465	TEMPSMART DC 48mL cartridge A3
012763	10001466	TEMPSMART DC 48mL cartridge A3.5
012764	10001467	TEMPSMART DC 48mL cartridge B1
012765	10001468	TEMPSMART DC 48mL cartridge BW
012766	10001469	TEMPSMART DC 10mL syringe A1
012767	10001470	TEMPSMART DC 10mL syringe A2
012768	10001471	TEMPSMART DC 10mL syringe A3
012769	10001472	TEMPSMART DC 10mL syringe B1
012770	10001473	TEMPSMART DC 48mL cartridge A1 EEP
012771	10001474	TEMPSMART DC 48mL cartridge A2 EEP
012772	10001475	TEMPSMART DC 48mL cartridge A3 EEP
012773	10001476	TEMPSMART DC 48mL cartridge A3.5 EEP
012774	10001477	TEMPSMART DC 48mL cartridge B1 EEP
012775	10001478	TEMPSMART DC 48mL cartridge BW EEP
012776	10001479	TEMPSMART DC 10mL syringe A1 EEP
012777	10001480	TEMPSMART DC 10mL syringe A2 EEP
012778	10001481	TEMPSMART DC 10mL syringe A3 EEP
012779	10001482	TEMPSMART DC 10mL syringe B1 EEP

