



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

TF153 01 June 2018
GMDN 16187

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

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

CERASMART 270

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

ISO 10477:2020 Dentistry -- Polymer-based crown and bridge materials

EN ISO 13485:2016 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

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.

CERASMART270 is Class **Ila** according to rule 8 of annex IX of the Council Directive.

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

Leuven,10/03/2021.....
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	Product description
012540	10001391	CERASMART270 12 A1 HT CEREC
012541	10001392	CERASMART270 12 A2 HT CEREC
012542	10001393	CERASMART270 12 A3 HT CEREC
012543	10001394	CERASMART270 12 A3.5 HT CEREC
012544	10001395	CERASMART270 12 B1 HT CEREC
012545	10001396	CERASMART270 12 A1 LT CEREC
012546	10001397	CERASMART270 12 A2 LT CEREC
012547	10001398	CERASMART270 12 A3 LT CEREC
012548	10001399	CERASMART270 12 A3.5 LT CEREC
012550	10001400	CERASMART270 12 B1 LT CEREC
012551	10001401	CERASMART270 12 BL CEREC
012552	10001402	CERASMART270 12 A1 HT UNIVERSAL
012553	10001403	CERASMART270 12 A2 HT UNIVERSAL
012554	10001404	CERASMART270 12 A3 HT UNIVERSAL
012555	10001405	CERASMART270 12 A3.5 HT UNIVERSAL
012556	10001406	CERASMART270 12 B1 HT UNIVERSAL
012557	10001407	CERASMART270 12 A1 LT UNIVERSAL
012558	10001408	CERASMART270 12 A2 LT UNIVERSAL
012559	10001409	CERASMART270 12 A3 LT UNIVERSAL
012560	10001410	CERASMART270 12 A3.5 LT UNIVERSAL
012562	10001411	CERASMART270 12 B1 LT UNIVERSAL
012563	10001412	CERASMART270 12 BL UNIVERSAL
012576	10001413	CERASMART270 14 A1 HT CEREC
012577	10001414	CERASMART270 14 A2 HT CEREC
012578	10001415	CERASMART270 14 A3 HT CEREC
012579	10001416	CERASMART270 14 A3.5 HT CEREC
012580	10001417	CERASMART270 14 B1 HT CEREC
012581	10001418	CERASMART270 14 A1 LT CEREC
012582	10001419	CERASMART270 14 A2 LT CEREC
012583	10001420	CERASMART270 14 A3 LT CEREC
012584	10001421	CERASMART270 14 A3.5 LT CEREC
012586	10001422	CERASMART270 14 B1 LT CEREC
012587	10001423	CERASMART270 14 BL CEREC
012588	10001424	CERASMART270 14 A1 HT UNIVERSAL
012589	10001425	CERASMART270 14 A2 HT UNIVERSAL
012590	10001426	CERASMART270 14 A3 HT UNIVERSAL
012591	10001427	CERASMART270 14 A3.5 HT UNIVERSAL
012592	10001428	CERASMART270 14 B1 HT UNIVERSAL
012593	10001429	CERASMART270 14 A1 LT UNIVERSAL
012594	10001430	CERASMART270 14 A2 LT UNIVERSAL
012595	10001431	CERASMART270 14 A3 LT UNIVERSAL
012596	10001432	CERASMART270 14 A3.5 LT UNIVERSAL
012598	10001433	CERASMART270 14 B1 LT UNIVERSAL
012599	10001434	CERASMART270 14 BL UNIVERSAL
012612	10001435	CERASMART270 14L A1 HT CEREC
012613	10001436	CERASMART270 14L A2 HT CEREC





012614	10001437	CERASMART270 14L A3 HT CEREC
012615	10001438	CERASMART270 14L A3.5 HT CEREC
012616	10001439	CERASMART270 14L B1 HT CEREC
012617	10001440	CERASMART270 14L A1 LT CEREC
012618	10001441	CERASMART270 14L A2 LT CEREC
012619	10001442	CERASMART270 14L A3 LT CEREC
012620	10001443	CERASMART270 14L A3.5 LT CEREC
012622	10001444	CERASMART270 14L B1 LT CEREC
012623	10001445	CERASMART270 14L BL CEREC
012624	10001446	CERASMART270 14L A1 HT UNIVERSAL
012625	10001447	CERASMART270 14L A2 HT UNIVERSAL
012626	10001448	CERASMART270 14L A3 HT UNIVERSAL
012627	10001449	CERASMART270 14L A3.5 HT UNIVERSAL
012628	10001450	CERASMART270 14L B1 HT UNIVERSAL
012629	10001451	CERASMART270 14L A1 LT UNIVERSAL
012630	10001452	CERASMART270 14L A2 LT UNIVERSAL
012631	10001453	CERASMART270 14L A3 LT UNIVERSAL
012632	10001454	CERASMART270 14L A3.5 LT UNIVERSAL
012634	10001455	CERASMART270 14L B1 LT UNIVERSAL
012635	10001456	CERASMART270 14L BL UNIVERSAL

