



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 10477:2018 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.

CERASMART 270 is Class **Ila** according to rule 8 of annex IX of the Council Directive.

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

Leuven,16/04/2019.....
Date


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



LIST OF PRODUCTS

Article code	Product description
012540	CERASMART270 12 CEREC A1 size12, 5p
012541	CERASMART270 12 CEREC HT A2 size12, 5p
012542	CERASMART270 12 CEREC HT A3 size12, 5p
012543	CERASMART270 12 CEREC HT A3.5 size12, 5p
012544	CERASMART270 12 CEREC HT B1 size12, 5p
012545	CERASMART270 12 CEREC LT A1 size12, 5p
012546	CERASMART270 12 CEREC LT A2 size12, 5p
012547	CERASMART270 12 CEREC LT A3 size12, 5p
012548	CERASMART270 12 CEREC LT B1 size12, 5p
012550	CERASMART270 12 CEREC LT B1 size12, 5p
012551	CERASMART270 12 CEREC BL size12, 5p
012576	CERASMART270 14 CEREC HT A1 size14, 5p
012577	CERASMART270 14 CEREC HT A2 size14, 5p
012578	CERASMART270 14 CEREC HT A3 size14, 5p
012579	CERASMART270 14 CEREC HT A3.5 size14, 5p
012580	CERASMART270 14 CEREC HT B1 size14, 5p
012581	CERASMART270 14 CEREC LT A1 size14, 5p
012582	CERASMART270 14 CEREC LT A2 size14, 5p
012583	CERASMART270 14 CEREC LT A3 size14, 5p
012584	CERASMART270 14 CEREC LT A3.5 size14, 5p
012586	CERASMART270 14 CEREC LT B1 size14, 5p
012587	CERASMART270 14 CEREC BL size14, 5p
012612	CERASMART270 14L CEREC HT A1 size14L, 5p
012613	CERASMART270 14L CEREC HT A2 size14L, 5p
012614	CERASMART270 14L CEREC HT A3 size14L, 5p
012615	CERASMART270 14L CEREC HT A3.5 size14L, 5p
012616	CERASMART270 14L CEREC HT B1 size14L, 5p
012617	CERASMART270 14L CEREC LT A1 size14L, 5p
012618	CERASMART270 14L CEREC LT A2 size14L, 5p
012619	CERASMART270 14L CEREC LT A3 size14L, 5p
012620	CERASMART270 14L CEREC LT A3.5 size14L, 5p
012622	CERASMART270 14L CEREC LT B1 size14L, 5p
012623	CERASMART270 14L CEREC BL size14L, 5p
012552	CERASMART270 12 UNIVERSAL HT A1 size12, 5p
012553	CERASMART270 12 UNIVERSAL HT A2 size12, 5p
012554	CERASMART270 12 UNIVERSAL HT A3 size12, 5p
012555	CERASMART270 12 UNIVERSAL HT A3.5 size12, 5p
012556	CERASMART270 12 UNIVERSAL HT B1 size12, 5p
012557	CERASMART270 12 UNIVERSAL LT A1 size12, 5p
012558	CERASMART270 12 UNIVERSAL LT A2 size12, 5p
012559	CERASMART270 12 UNIVERSAL LT A3 size12, 5p
012560	CERASMART270 12 UNIVERSAL LT A3.5 size12, 5p
012562	CERASMART270 12 UNIVERSAL LT B1 size12, 5p
012563	CERASMART270 12 UNIVERSAL BL size12, 5p
012588	CERASMART270 14 UNIVERSAL HT A1 size14, 5p
012589	CERASMART270 14 UNIVERSAL HT A2 size14, 5p
012590	CERASMART270 14 UNIVERSAL HT A3 size14, 5p
012591	CERASMART270 14 UNIVERSAL HT A3.5 size14, 5p
012592	CERASMART270 14 UNIVERSAL HT B1 size14, 5p



012593	CERASMART270 14 UNIVERSAL LT A1 size14, 5p
012594	CERASMART270 14 UNIVERSAL LT A2 size14, 5p
012595	CERASMART270 14 UNIVERSAL LT A3 size14, 5p
012596	CERASMART270 14 UNIVERSAL LT A3.5 size14, 5p
012598	CERASMART270 14 UNIVERSAL LT B1 size14, 5p
012599	CERASMART270 14 UNIVERSAL BL size14, 5p
012624	CERASMART270 14L UNIVERSAL HT A1 size14L, 5b
012625	CERASMART270 14L UNIVERSAL HT A2 size14L, 5
012626	CERASMART270 14L UNIVERSAL HT A3 size14L, 5
012627	CERASMART270 14L UNIVERSAL A3.5 size14L, 5p
012628	CERASMART270 14L UNIVERSAL HT B1 size14L, 5p
012629	CERASMART270 14L UNIVERSAL LT A1 size14L, 5p
012630	CERASMART270 14L UNIVERSAL LT A2 size14L, 5
012631	CERASMART270 14L UNIVERSAL LT A3 size14L, 5p
012632	CERASMART270 14L UNIVERSAL LT A3.5 size14L, 5p
012634	CERASMART270 14L UNIVERSAL LT B1 size14L, 5p
012635	CERASMART270 14L UNIVERSAL BL size14L, 5p
890451	CERASMART270 CEREC Sample HT A3 – 14, 1pcs
890452	CERASMART270 CEREC Sample LT A2 – 14, 1pcs
890453	CERASMART270 Universal Sample HT A3 – 14, 1pcs
890454	CERASMART270 Universal Sample LT A2 – 14, 1pcs
901594	CERASMART270 Advanced Kit



