

EC Declaration of Conformity

We,

Vertex-Dental B.V.
Centurionbaan 190
3769 AV Soesterberg,
The Netherlands

Hereby declare under our sole responsibility that the CE marked product to which this declaration relates,

Vertex Castapress

Member of the productfamily Denture base resins, Self Cured
Productcodes are available in annex I.

has been classified as Class IIa, according to Annex IX, rule 5, and is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC concerning medical devices as amended by Directive 2007/47/EC.

and is conformity with the standards applicable to the device listed in TF02-LAS_v01.

and is subject to the procedure set out in Annex II (excluding section 4) of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

This declaration is made on base of the EC Certificate Full Quality Assurance System
BE19/819943693 issue 7 valid until May 24th 2024 delivered by:

Notified Body n° 1639
SGS Belgium NV
SGS House
Noorderlaan 87
2030 Antwerp
Belgium

This Declaration of conformity covers batches produced as of batches:
WX435P01 for the powder
WX435L01 for the liquid

Soesterberg, October 29 2021

Mrs. L. Vloet-Emonts
Person Responsible for Regulatory Compliance

Annex I: Product references Vertex Castapress

Description	size	articlenumber
Vertex Castapress / 2	25000	ACPP0225000
Vertex Castapress / 3	50000	ACPP0350000
Vertex Castapress / 6	50000	ACPP0650000
Vertex Castapress / 7	50000	ACPP0750000
Vertex Castapress / 8	50000	ACPP0850000
Vertex Castapress /10	50000	ACPP1050000
Vertex Castapress /12	50000	ACPP1250000
Vertex Castapress /15	50000	ACPP1550000
Vertex Castapress /16	50000	ACPP1650000
Vertex Castapress / 17	4000	ACPP17GDS04000
Vertex Castapress / 20	4000	ACPP20GDS04000
Vertex Castapress / 20	25000	ACPP20GDS25000
Vertex Castapress / 20	50000	ACPP20GDS50000
Vertex Castapress /40	1000	ACPP4001000
Vertex Castapress /40	25000	ACPP4025000
Vertex Castapress /J6V	1000	ACPPJ601000
Vertex Castapress 200lt	200000	ACPV200000
Vertex Castapress	25000	ACPV25000
Vertex Castapress / 2	1000	AVCPP0201000
Vertex Castapress / 3	500	AVCPP0300500
Vertex Castapress / 3	1000	AVCPP0301000
Vertex Castapress / 3	4000	AVCPP0304000
Vertex Castapress / 3	25000	AVCPP0325000
Vertex Castapress / 4	500	AVCPP0400500
Vertex Castapress / 4	1000	AVCPP0401000
Vertex Castapress / 4	4000	AVCPP0404000
Vertex Castapress / 4	25000	AVCPP0425000
Vertex Castapress / 5	500	AVCPP0500500
Vertex Castapress / 5	1000	AVCPP0501000
Vertex Castapress / 5	4000	AVCPP0504000
Vertex Castapress / 5	25000	AVCPP0525000
Vertex Castapress / 6	500	AVCPP0600500
Vertex Castapress / 6	1000	AVCPP0601000
Vertex Castapress / 6	4000	AVCPP0604000
Vertex Castapress / 6	25000	AVCPP0625000
Vertex Castapress / 7	500	AVCPP0700500
Vertex Castapress / 7	1000	AVCPP0701000
Vertex Castapress / 7	4000	AVCPP0704000
Vertex Castapress / 7	25000	AVCPP0725000
Vertex Castapress / 8	500	AVCPP0800500
Vertex Castapress / 8	1000	AVCPP0801000
Vertex Castapress / 8	4000	AVCPP0804000
Vertex Castapress / 8	25000	AVCPP0825000
Vertex Castapress /10	500	AVCPP1000500

FM 505 – Declaration of Conformity Class IIa v4

Description	size	articlenumber
Vertex Castapress /10	1000	AVCPP1001000
Vertex Castapress /10	4000	AVCPP1004000
Vertex Castapress /10	25000	AVCPP1025000
Vertex Castapress /12	4000	AVCPP1204000
Vertex Castapress	250	AVCPV00250
Vertex Castapress	1000	AVCPV01000
Vertex Castapress	5000	AVCPV05000