

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 BasiQ20

Member of the productfamily Denture base resins, Heat 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 in conformity with EN ISO 13485:2016; EN 1041:2008 +A1:2013; EN ISO 1641:2009; EN ISO 15223-1: 2016; EN ISO 15223-2:2010; EN IEC 62366-1:2015; IEC/TR 62366-2:2016; EN ISO 179-1:2010; EN ISO 20795-1:2013; EN ISO 22112:2006; EN ISO 7405:2009 /A1:2013; EN ISO 7491:2000; EN ISO 14971:2012; ISO 10993-1:2018; EN ISO 10993-3:2014; EN ISO 10993-5:2009; EN ISO 10993-10:2010; EN ISO 10993-17:2009 and EN ISO 10993-18:2009.

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:

WX224P01 for the powder

WX224L01 for the liquid

Soesterberg, June 3rd 2021

Mrs. L. Vloet-Emonts

Person Responsible for Regulatory Compliance


VERTEX-DENTAL B.V.
Centurionbaan 190
3769 AV Soesterberg
THE NETHERLANDS
Tel. +31 (0) 88 6160 440

FM 505 – Declaration of Conformity Class IIa v4

Annex I: Product references Vertex BasiQ20

Description	size	articlenumber
Vertex BasiQ 20 liquid	250	DBQ20V00250
Vertex BasiQ 20 liquid	1000	DBQ20V01000
Vertex BasiQ 20 liquid	5000	DBQ20V05000
Vertex BasiQ 20 liquid	25000	DBQ20V25000
Vertex BasiQ 20 / 2	500	DBQPD200200500
Vertex BasiQ 20 / 2	1000	DBQPD200201000
Vertex BasiQ 20 / 2	4000	DBQPD200204000
Vertex BasiQ 20 / 3	500	DBQPD200300500
Vertex BasiQ 20 / 3	1000	DBQPD200301000
Vertex BasiQ 20 / 3	4000	DBQPD200304000
Vertex BasiQ 20 / 4	1000	DBQPD200401000
Vertex BasiQ 20 / 5	50000	DBQPD200550000
Vertex BasiQ 20 / 7	500	DBQPD200700500
Vertex BasiQ 20 / 7	1000	DBQPD200701000
Vertex BasiQ 20 / 7	50000	DBQPD200750000
Vertex BasiQ 20 / 10	500	DBQPD201000500
Vertex BasiQ 20 / 10	1000	DBQPD201001000
Vertex BasiQ 20 / 10	4000	DBQPD201004000
Vertex BasiQ 20 / 10	25000	DBQPD201025000
Vertex BasiQ 20 / 28	500	DBQPD202800500
Vertex BasiQ 20 / 28	1000	DBQPD202801000
Vertex BasiQ 20 / J7V	50000	DBQPD20J750000