

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 ThermoSens Rigid

Productcodes are available in the annex.

has been classified as Class I, 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; EN ISO 10993-1:2009/AC2010; EN ISO 10993-3:2014; EN ISO 10993-5:2009 and EN ISO 10993-10:2010.

and is subject to the procedure set out in Annex VII of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

This declaration is made on the base of the quality assurance certificate ISO 13485:2016
N° BE12/223574929 Issue 4 valid until 17-12-2021 delivered by:

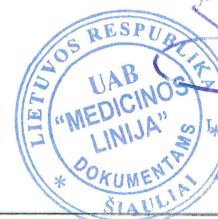
SGS United Kingdom Ltd. Systems & Services Certification
Rossmore Business Park
Ellesmere Port
Cheshire CH65 3EN
United Kingdom

This Declaration of conformity covers batches produced as of batches:
XG053T01

Soesterberg, January 30th 2019

 VERTEX-DENTAL B.V.
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Mrs. L. Vloet - Emonts
Manager Quality Assurance & Regulatory Affairs



KOPIJA TIKRA

Logistikos vadybininkė -
administratore
Aida Palušienė

EB ATITIKTIES DEKLARACIJA

Mes,

Vertex-Dental B.V.
Centurionbaan 190
3769 AV Soesterberg
Nyderlandai

su visa atsakomybe deklaruojame, kad produktas paženklintas CE ženklu, siejamas su šia deklaracija

Vertex ThermoSens Rigid

Prekių kodai pateikiami priede.

priskiriamas I Klasei pagal IX Priedo, 5 Taisyklę ir atitinka esminius Tarybos Direktyvos 93/42/EEB (pakeičiančios Direktyvą 2007/47/EB) medicinos priemonės reikalavimus ir nuostatas.

ir atitinka standartus: 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; EN ISO 10993-1:2009/AC2010; EN ISO 10993-3:2014; EN ISO 10993-5:2009 and EN ISO 10993-10:2010.

ir yra procedūros priežiūros objektas kaip nustatyta VII Priede Tarybos Direktyvos 93/42/EEB (pakeičiančios Direktyvą 2007/47/EB).

Ši deklaracija parengta vadovaujantis kokybės užtikrinimo sertifikatu ISO 13485:2016 Nr. BE12/223574929, 4 Leidimo, galiojančiu iki 2021-12-17, išduotu:

SGS United Kingdom Ltd.
Sertifikavimo sistemos ir paslaugos
Rossmore Business Park
Ellesmere Port
Cheshire CH65 3EN
Jungtinė karalystė

Ši atitikties deklaracija apima šias gamybos partijas:
XG053T01

Soesterberg, 2019 m. sausio 30 d.

/parašas/spaudas/
p. L. Vloet - Emonts
Kokybės užtikrinimo ir reglamentavimo reikalų vadovas

KOPIJA TIKRA



Annex I: Product references Vertex ThermoSens Rigid

Description	size	articlenumber
ThermoSens Rigid / T03	200	TVTSR00200T03
ThermoSens Rigid / T05	200	TVTSR00200T05
ThermoSens Rigid / T07	200	TVTSR00200T07
ThermoSens Rigid / T10	200	TVTSR00200T10
ThermoSens Rigid / T27	200	TVTSR00200T27
ThermoSens Rigid / TA1	200	TVTSR00200TA1
ThermoSens Rigid / TA2	200	TVTSR00200TA2
ThermoSens Rigid / TA3	200	TVTSR00200TA3
ThermoSens Rigid / TA3.5	200	TVTSR00200TA3.5
ThermoSens Rigid / TBL	200	TVTSR00200TBL
ThermoSens Rigid / TCL - clear	200	TVTSR00200TCL
ThermoSens Rigid / TCLV - clear veined	200	TVTSR00200TCLV
ThermoSens / TS - soft pink	200	TVTSR00200TS
ThermoSens Rigid / TTR - transp. pink	200	TVTSR00200TTR
ThermoSens / TTRV - transp. pink veined	200	TVTSR00200TTRV
ThermoSens Rigid / T03	400	TVTSR00400T03
ThermoSens Rigid / T05	400	TVTSR00400T05
ThermoSens Rigid / T07	400	TVTSR00400T07
ThermoSens Rigid / T10	400	TVTSR00400T10
ThermoSens Rigid / T27	400	TVTSR00400T27
ThermoSens Rigid / TA1	400	TVTSR00400TA1
ThermoSens Rigid / TA2	400	TVTSR00400TA2
ThermoSens Rigid / TA3	400	TVTSR00400TA3
ThermoSens Rigid / TA3.5	400	TVTSR00400TA3.5
ThermoSens Rigid / TBL	400	TVTSR00400TBL
ThermoSens Rigid / TCL - clear	400	TVTSR00400TCL
ThermoSens Rigid / TCLV - clear veined	400	TVTSR00400TCLV
ThermoSens Rigid / TS - soft pink	400	TVTSR00400TS
ThermoSens Rigid / TTR - transp. pink	400	TVTSR00400TTR
ThermoSens / TTRV - transp. pink veined	400	TVTSR00400TTRV
ThermoSens Rigid / T03	1000	TVTSR01000T03
ThermoSens Rigid / T05	1000	TVTSR01000T05
ThermoSens Rigid / T07	1000	TVTSR01000T07
ThermoSens Rigid / T10	1000	TVTSR01000T10

Description	size	articlenumber
ThermoSens Rigid / T27	1000	TVTSR01000T27
ThermoSens Rigid / TA1	1000	TVTSR01000TA1
ThermoSens Rigid / TA2	1000	TVTSR01000TA2
ThermoSens Rigid / TA3	1000	TVTSR01000TA3
ThermoSens Rigid / TA3.5	1000	TVTSR01000TA3.5
ThermoSens Rigid / TBL	1000	TVTSR01000TBL
ThermoSens Rigid / TCL - clear	1000	TVTSR01000TCL
ThermoSens / TCLV - clear veined	1000	TVTSR01000TCLV
ThermoSens Rigid / TS - soft pink	1000	TVTSR01000TS
ThermoSens Rigid / TTR - transp. pink	1000	TVTSR01000TTR
ThermoSens Rigid / TTRV - transp. pink veined	1000	TVTSR01000TTRV
ThermoSens Rigid / T03	4000	TVTSR04000T03
ThermoSens Rigid / T05	4000	TVTSR04000T05
ThermoSens Rigid / T07	4000	TVTSR04000T07
ThermoSens Rigid / T10	4000	TVTSR04000T10
ThermoSens Rigid / T27	4000	TVTSR04000T27
ThermoSens Rigid / TA1	4000	TVTSR04000TA1
ThermoSens Rigid / TA2	4000	TVTSR04000TA2
ThermoSens Rigid / TA3	4000	TVTSR04000TA3
ThermoSens Rigid / TA3.5	4000	TVTSR04000TA3.5
ThermoSens Rigid / TBL	4000	TVTSR04000TBL
ThermoSens Rigid / TCL - clear	4000	TVTSR04000TCL
ThermoSens Rigid / TCLV - clear veined	4000	TVTSR04000TCLV
ThermoSens Rigid / TS - soft pink	4000	TVTSR04000TS
ThermoSens Rigid / TTR - transp. pink	4000	TVTSR04000TTR
ThermoSens Rigid / TTRV - transp. pink veined	4000	TVTSR04000TTRV
ThermoSens Rigid / T03	20000	TVTSR20000T03
ThermoSens Rigid / T05	20000	TVTSR20000T05
ThermoSens Rigid / T07	20000	TVTSR20000T07
ThermoSens Rigid / T10	20000	TVTSR20000T10
ThermoSens Rigid / TA1	20000	TVTSR20000TA1
ThermoSens Rigid / TA2	20000	TVTSR20000TA2
ThermoSens Rigid / TA3	20000	TVTSR20000TA3
ThermoSens Rigid / TA3.5	20000	TVTSR20000TA3.5

Description	size	articlenumber
ThermoSens Rigid / TBL	20000	TVTSR20000TBL
ThermoSens Rigid / TCL - clear	20000	TVTSR20000TCL
ThermoSens Rigid / TCLV - clear veined	20000	TVTSR20000TCLV
ThermoSens Rigid / TS - soft pink	20000	TVTSR20000TS
ThermoSens Rigid / TTR - transp. pink	20000	TVTSR20000TTR
ThermoSens Rigid / TTRV - transp. pink veined	20000	TVTSR20000TTRV
ThermoSens Rigid / T03	22 L	TVTSR22LT03
ThermoSens Rigid / T05	22 L	TVTSR22LT05
ThermoSens Rigid / T07	22 L	TVTSR22LT07
ThermoSens Rigid / T10	22 L	TVTSR22LT10
ThermoSens Rigid / TA1	22 L	TVTSR22LTA1
ThermoSens Rigid / TA2	22 L	TVTSR22LTA2
ThermoSens Rigid / TA3	22 L	TVTSR22LTA3
ThermoSens Rigid / TA3.5	22 L	TVTSR22LTA3.5
ThermoSens Rigid / TBL	22 L	TVTSR22LTBL
ThermoSens Rigid / TCL - clear	22 L	TVTSR22LTCL
ThermoSens Rigid / TCLV - clear veined	22 L	TVTSR22LTCLV
ThermoSens Rigid / TS - soft pink	22 L	TVTSR22LTS
ThermoSens Rigid / TTR - transp. pink	22 L	TVTSR22LTTR
ThermoSens Rigid / TTRV - transp. pink veined	22 L	TVTSR22LTTRV
ThermoSens Rigid / T03	22 M	TVTSR22MT03
ThermoSens Rigid / T05	22 M	TVTSR22MT05
ThermoSens Rigid / T07	22 M	TVTSR22MT07
ThermoSens Rigid / T10	22 M	TVTSR22MT10
ThermoSens Rigid / TA1	22 M	TVTSR22MTA1
ThermoSens Rigid / TA2	22 M	TVTSR22MTA2
ThermoSens Rigid / TA3	22 M	TVTSR22MTA3
ThermoSens Rigid / TA3.5	22 M	TVTSR22MTA3.5
ThermoSens Rigid / TBL	22 M	TVTSR22MTBL
ThermoSens Rigid / TCL - clear	22 M	TVTSR22MTCL
ThermoSens Rigid / TTRV - transp. pink veined	22 M	TVTSR22MTTRV
ThermoSens Rigid / T03	22 XL	TVTSR22XLT03
ThermoSens Rigid / T05	22 XL	TVTSR22XLT05
ThermoSens Rigid / T07	22 XL	TVTSR22XLT07
ThermoSens Rigid / T10	22 XL	TVTSR22XLT10

Description	size	articlenumber
ThermoSens Rigid / TA1	22 XL	TVTSR22XLTA1
ThermoSens Rigid / TA2	22 XL	TVTSR22XLTA2
ThermoSens Rigid / TA3	22 XL	TVTSR22XLTA3
ThermoSens Rigid / TA3.5	22 XL	TVTSR22XLTA3.5
ThermoSens Rigid / TBL	22 XL	TVTSR22XL TBL
ThermoSens / TCL - clear	22 XL	TVTSR22XL TCL
ThermoSens Rigid / TCLV - clear veined	22 XL	TVTSR22XL TCLV
ThermoSens Rigid / TS - soft pink	22 XL	TVTSR22XL TS
ThermoSens Rigid / TTR - transp. pink	22 XL	TVTSR22XL TTR
ThermoSens Rigid / TTRV - tr. pink veined	22 XL	TVTSR22XL TTRV
ThermoSens Rigid / T03	25 L	TVTSR25LT03
ThermoSens Rigid / T05	25 L	TVTSR25LT05
ThermoSens Rigid / T07	25 L	TVTSR25LT07
ThermoSens Rigid / T10	25 L	TVTSR25LT10
ThermoSens Rigid / TA1	25 L	TVTSR25LTA1
ThermoSens Rigid / TA2	25 L	TVTSR25LTA2
ThermoSens Rigid / TA3	25 L	TVTSR25LTA3
ThermoSens Rigid / TA3.5	25 L	TVTSR25LTA3.5
ThermoSens Rigid / TBL	25 L	TVTSR25LTBL
ThermoSens Rigid / TCL - clear	25 L	TVTSR25LTCL
ThermoSens Rigid / TCLV - clear veined	25 L	TVTSR25LTCLV
ThermoSens Rigid / TS - soft pink	25 L	TVTSR25LTS
ThermoSens Rigid / TTR - transp. pink	25 L	TVTSR25LTTR
ThermoSens Rigid / TTRV - transp. pink veined	25 L	TVTSR25LTTRV
ThermoSens Rigid / T03	25 M	TVTSR25MT03
ThermoSens Rigid / T05	25 M	TVTSR25MT05
ThermoSens Rigid / T07	25 M	TVTSR25MT07
ThermoSens Rigid / T10	25 M	TVTSR25MT10
ThermoSens Rigid / TA1	25 M	TVTSR25MTA1
ThermoSens Rigid / TA2	25 M	TVTSR25MTA2
ThermoSens Rigid / TA3	25 M	TVTSR25MTA3
ThermoSens Rigid / TA3.5	25 M	TVTSR25MTA3.5
ThermoSens Rigid / TBL	25 M	TVTSR25MTBL
ThermoSens Rigid / TCL - clear	25 M	TVTSR25MTCL
ThermoSens Rigid / TCLV - clear veined	25 M	TVTSR25MTCLV

Declaration of Conformity Class I

FM 504 – Declaration of Conformity Class I V1

Description	size	articlenumber	Product name	size	articlenumber
ThermoSens Rigid / TS - soft pink	25 M	TVTSR25MTS	ThermoSens Rigid / TA3.5	25 XL	TVTSR25XLTA3.5
ThermoSens Rigid / TTR - transp. pink	25 M	TVTSR25MTTR	ThermoSens Rigid / TBL	25 XL	TVTSR25XLTL
ThermoSens Rigid / TTRV - transp. pink veined	25 M	TVTSR25MTTRV	ThermoSens Rigid / TCL - clear	25 XL	TVTSR25XLTC
ThermoSens Rigid / T03	25 XL	TVTSR25XLT03	ThermoSens Rigid / TCLV - clear veined	25 XL	TVTSR25XLTCV
ThermoSens Rigid / T05	25 XL	TVTSR25XLT05	ThermoSens Rigid / TS - soft pink	25 XL	TVTSR25XLTS
ThermoSens Rigid / T07	25 XL	TVTSR25XLT07	ThermoSens Rigid / TTR - transp. pink	25 XL	TVTSR25XLTTR
ThermoSens Rigid / T10	25 XL	TVTSR25XLT10	ThermoSens Rigid / TTRV - tr. pink veined	25 XL	TVTSR25XLTTRV
ThermoSens Rigid / TA1	25 XL	TVTSR25XLTA1	ThermoSens Rigid 20000/ T27	20000	TVTSR20000T27
ThermoSens Rigid / TA2	25 XL	TVTSR25XLTA2	ThermoSens Rigid 22mm Medium/ TS – soft pink	22 M	TVTSR22MTS
ThermoSens Rigid / TA3	25 XL	TVTSR25XLTA3	ThermoSens Rigid 22mm Medium/ TTR – transp. pink	22 M	TVTSR22MTTR

KOPIJA TIKRA



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Aida Petilienė