

## Declaration of conformity

CE 0123

Manufacturer Address	Wieland Dental + Technik GmbH & Co. KG Lindenstrasse 2 75175 Pforzheim Germany	
Product	<b>Zenostar Zr Translucent</b> <b>Zenostar MO</b> <b>Zenostar Color Zr</b> <b>Zenostar VisualiZr</b> <b>Zenostar MT Color</b>	<b>Zenostar T</b> <b>Zenostar MT</b>
Type of material	Ceramic blanks for dental restorations. Coloring liquid for staining of anatomic zirconium dioxide restorations.	
Product category	dental ceramics staining liquids for dental ceramics	
Classification	Medical Device Class IIa	

We hereby declare under our exclusive responsibility that the above mentioned products meet the provisions of the following EC Council Directives and its implementation in national law. All supporting documentation is retained on the premises of the manufacturer and the notified body.

Directives Medical Device Directive 93/42/EEC, Annex II. 3

Notified Body Address TÜV SÜD Product Service GmbH  
Ridlerstrasse 65  
80339 München  
Deutschland

Place, Valid from Pforzheim, January 1<sup>st</sup> 2016  
Replaces version of: October 31<sup>st</sup> 2014

Valid until December, 16<sup>th</sup> 2020

Signature		
Name	Michael Hammer	Martin Senger
Position	Managing Director	Sicherheitsbeauftragter (Product Safety Officer)

Date	Dec 18 <sup>th</sup> 2015	Dec 18 <sup>th</sup> 2015
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## Attachment to Declaration of conformity

Product **Zenostar Zr Translucent  
Zenostar T  
Zenostar MO  
Zenostar MT  
Zenostar Color Zr  
Zenostar VisualiZr  
Zenostar MT Color**

Dated Dec 18<sup>th</sup> 2015

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REF	Description
659112	Zenostar Zr Translucent pure 10 mm
659113	Zenostar Zr Translucent pure 12 mm
659114	Zenostar Zr Translucent pure 14 mm
659115	Zenostar Zr Translucent pure 16 mm
659116	Zenostar Zr Translucent pure 18 mm
659117	Zenostar Zr Translucent pure 20 mm
659118	Zenostar Zr Translucent pure 25 mm
662757	Zenostar Zr Translucent light 10 mm
660011	Zenostar Zr Translucent light 12 mm
659119	Zenostar Zr Translucent light 14 mm
660012	Zenostar Zr Translucent light 16 mm
659120	Zenostar Zr Translucent light 18 mm
659121	Zenostar Zr Translucent light 20 mm
659122	Zenostar Zr Translucent light 25 mm

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REF	Description
660013	Zenostar Zr Translucent medium 10 mm
660014	Zenostar Zr Translucent medium 12 mm
659123	Zenostar Zr Translucent medium 14 mm
660015	Zenostar Zr Translucent medium 16 mm
659124	Zenostar Zr Translucent medium 18 mm
659125	Zenostar Zr Translucent medium 20 mm
659126	Zenostar Zr Translucent medium 25 mm
662758	Zenostar Zr Translucent intense 10 mm
660016	Zenostar Zr Translucent intense 12 mm
659127	Zenostar Zr Translucent intense 14 mm
660017	Zenostar Zr Translucent intense 16 mm
659128	Zenostar Zr Translucent intense 18 mm
659129	Zenostar Zr Translucent intense 20 mm
659130	Zenostar Zr Translucent intense 25mm

662759	Zenostar Zr Translucent sun 10 mm
660018	Zenostar Zr Translucent sun 12 mm
659131	Zenostar Zr Translucent sun 14 mm
660019	Zenostar Zr Translucent sun 16 mm
660020	Zenostar Zr Translucent sun 18 mm
660021	Zenostar Zr Translucent sun 20 mm
660022	Zenostar Zr Translucent sun 25 mm
662760	Zenostar Zr Translucent sun chroma 10 mm
660023	Zenostar Zr Translucent sun chroma 12 mm

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REF	Description
659132	Zenostar Zr Translucent sun chroma 14 mm
660024	Zenostar Zr Translucent sun chroma 16 mm
660025	Zenostar Zr Translucent sun chroma 18 mm
660026	Zenostar Zr Translucent sun chroma 20 mm
660027	Zenostar Zr Translucent sun chroma 25 mm
670237	Zenostar Zr T pure 14mm no step
670238	Zenostar Zr T pure 18mm no step
670239	Zenostar Zr T pure 25mm no step
670241	Zenostar Zr T light 14mm no step
670242	Zenostar Zr T light 18mm no step
670243	Zenostar Zr T light 25mm no step
670245	Zenostar Zr T medium 14mm no step
670246	Zenostar Zr T medium 18mm no step
670247	Zenostar Zr T medium 25mm no step
670249	Zenostar Zr T intense 14mm no step
670250	Zenostar Zr T intense 18mm no step
670251	Zenostar Zr T intense 25mm no step
670253	Zenostar Zr T sun 14mm no step
670254	Zenostar Zr T sun 18mm no step
670255	Zenostar Zr T sun 25mm no step
670257	Zenostar Zr T sun chroma 14mm no step
670258	Zenostar Zr T sun chroma 18mm no step
670259	Zenostar Zr T sun chroma 25mm no step

REF	Description
667848	Zenostar T 0 98.5-10mm/1
667855	Zenostar T 0 98.5-12mm/1

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REF	Description
667862	Zenostar T 0 98.5-14mm/1
667869	Zenostar T 0 98.5-16mm/1
667876	Zenostar T 0 98.5-18mm/1
667883	Zenostar T 0 98.5-20mm/1
667890	Zenostar T 0 98.5-25mm/1
667849	Zenostar T 1 98.5-10mm/1
667856	Zenostar T 1 98.5-12mm/1
667863	Zenostar T 1 98.5-14mm/1
667870	Zenostar T 1 98.5-16mm/1
667877	Zenostar T 1 98.5-18mm/1
667884	Zenostar T 1 98.5-20mm/1
667891	Zenostar T 1 98.5-25mm/1
667850	Zenostar T 2 98.5-10mm/1
667857	Zenostar T 2 98.5-12mm/1
667864	Zenostar T 2 98.5-14mm/1
667871	Zenostar T 2 98.5-16mm/1
667878	Zenostar T 2 98.5-18mm/1
667885	Zenostar T 2 98.5-20mm/1
667892	Zenostar T 2 98.5-25mm/1
667851	Zenostar T 3 98.5-10mm/1
667858	Zenostar T 3 98.5-12mm/1
667865	Zenostar T 3 98.5-14mm/1

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REF	Description
667872	Zenostar T 3 98.5-16mm/1
667879	Zenostar T 3 98.5-18mm/1
667886	Zenostar T 3 98.5-20mm/1
667893	Zenostar T 3 98.5-25mm/1
667852	Zenostar T 4 98.5-10mm/1
667859	Zenostar T 4 98.5-12mm/1
667866	Zenostar T 4 98.5-14mm/1
667873	Zenostar T 4 98.5-16mm/1
667880	Zenostar T 4 98.5-18mm/1
667887	Zenostar T 4 98.5-20mm/1
667894	Zenostar T 4 98.5-25mm/1

667853	Zenostar T sun 98.5-10mm/1
667860	Zenostar T sun 98.5-12mm/1
667867	Zenostar T sun 98.5-14mm/1
667874	Zenostar T sun 98.5-16mm/1
667881	Zenostar T sun 98.5-18mm/1
667888	Zenostar T sun 98.5-20mm/1
667895	Zenostar T sun 98.5-25mm/1
667854	Zenostar T sun chroma 98.5-10mm/1
667861	Zenostar T sun chroma 98.5-12mm/1
667868	Zenostar T sun chroma 98.5-14mm/1
667875	Zenostar T sun chroma 98.5-16mm/1

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REF	Description
667882	Zenostar T sun chroma 98.5-18mm/1
667889	Zenostar T sun chroma 98.5-20mm/1
667896	Zenostar T sun chroma 98.5-25mm/1

REF	Description
665246	Zenostar MO 0 98.5-10mm/1
665251	Zenostar MO 0 98.5-14mm/1
665256	Zenostar MO 0 98.5-18mm/1
665261	Zenostar MO 0 98.5-20mm/1
665266	Zenostar MO 0 98.5-25mm/1
665247	Zenostar MO 1 98.5-10mm/1
665252	Zenostar MO 1 98.5-14mm/1
665257	Zenostar MO 1 98.5-18mm/1
665262	Zenostar MO 1 98.5-20mm/1
665267	Zenostar MO 1 98.5-25mm/1
665248	Zenostar MO 2 98.5-10mm/1
665253	Zenostar MO 2 98.5-14mm/1
665258	Zenostar MO 2 98.5-18mm/1
665263	Zenostar MO 2 98.5-20mm/1
665268	Zenostar MO 2 98.5-25mm/1
665249	Zenostar MO 3 98.5-10mm/1

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REF	Description
665254	Zenostar MO 3 98.5-14mm/1
665259	Zenostar MO 3 98.5-18mm/1
665264	Zenostar MO 3 98.5-20mm/1
665269	Zenostar MO 3 98.5-25mm/1
665250	Zenostar MO 4 98.5-10mm/1
665255	Zenostar MO 4 98.5-14mm/1
665260	Zenostar MO 4 98.5-18mm/1
665265	Zenostar MO 4 98.5-20mm/1
665270	Zenostar MO 4 98.5-25mm/1

REF	Description
678841	Zenostar MT 0 98.5-14mm/1
678849	Zenostar MT 0 98.5-18mm/1

REF	Description
659427	Zenostar Color Zr A1 100 ml
659428	Zenostar Color Zr A2 100 ml
659429	Zenostar Color Zr A3 100 ml
659430	Zenostar Color Zr A3,5 100 ml
659431	Zenostar Color Zr A4 100 ml
659432	Zenostar Color Zr B1 100 ml

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REF	Description
659433	Zenostar Color Zr B2 100 ml
659434	Zenostar Color Zr B3 100 ml
659435	Zenostar Color Zr B4 100 ml
659436	Zenostar Color Zr C1 100 ml
659437	Zenostar Color Zr C2 100 ml
659438	Zenostar Color Zr C3 100 ml
659439	Zenostar Color Zr C4 100 ml
659440	Zenostar Color Zr D2 100 ml
659441	Zenostar Color Zr D3 100 ml
659442	Zenostar Color Zr D4 100 ml
659444	Zenostar Color Zr brown 30 ml
659445	Zenostar Color Zr orange 30 ml
659446	Zenostar Color Zr grey-violet 30 ml
659425	Zenostar Color Zr white 30 ml
659447	Zenostar Color Zr ivory 30 ml

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REF	Description
666343	Zenostar VisualiZr red 15ml
666344	Zenostar VisualiZr blue 15ml
666345	Zenostar VisualiZr yellow 15ml

REF	Description
681050	Zenostar MT Color A1 60ml
681051	Zenostar MT Color A2 60ml
681052	Zenostar MT Color A3 60ml
681053	Zenostar MT Color A3,5 60ml
681054	Zenostar MT Color A4 60ml
681055	Zenostar MT Color B1 60ml
681056	Zenostar MT Color B2 60ml
681057	Zenostar MT Color B3 60ml
681058	Zenostar MT Color B4 60ml
681059	Zenostar MT Color C1 60ml
681060	Zenostar MT Color C2 60ml
681061	Zenostar MT Color C3 60ml
681062	Zenostar MT Color C4 60ml
681063	Zenostar MT Color D2 60ml
681064	Zenostar MT Color D3 60ml
681065	Zenostar MT Color D4 60ml

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REF	Description
681165	Zenostar MT Color Impulse blue
681166	Zenostar MT Color Impulse violet
681167	Zenostar MT Color Impulse grey
681168	Zenostar MT Color Impulse orange
681169	Zenostar MT Color Impulse brown

Place, Valid from

Pforzheim, May 9<sup>th</sup> 2016  
Replaces version of: April 14<sup>th</sup> 2016

Signature



Name

Sascha  
Cramer von Clausbruch

Frank Wokkittel

Position

Product Management

Regulatory Affairs

Date

May 9<sup>th</sup> 2016

May 9<sup>th</sup> 2016

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