


## EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

We hereby declare that this EU Declaration of Conformity is issued under the sole responsibility of the manufacturer and the below mentioned products meet the provisions of the EU Regulation above. All supporting documentation is retained on the premises of the manufacturer and the Notified Body.

<b>Products</b>	Preference anterior, Preference posterior
<b>Basic-UDI-DI</b>	763081342APROS002VE
<b>Document-ID</b>	OTCS195395372
<b>Document Version</b>	1.0

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EU Declaration of Conformity Information	
<b>SRN</b>	CH-MF-000015795
<b>Intended Purpose</b>	Replacement of missing teeth with removable dentures
<b>Category (MDCG 2019-14)</b>	MDN 1209      Non-active non-implantable dental materials
<b>EMDN Code + term</b>	Q010699 Materials for the preparation of custom-made dental devices - other
<b>MDS Code</b>	MDS 1007
<b>MDT Code</b>	MDT 2002 MDT 2006 MDT 2011
<b>EU Risk Classification (MDR Annex VIII)</b>	Medical Device Class IIa <span style="border: 1px solid black; padding: 2px;">CE 0123</span>
<b>Conformity Assessment Procedure (MDR Annex IX)</b>	Quality Management System
<b>Notified Body Address</b>	<b>TÜV SÜD Product Service GmbH</b> Ridlerstrasse 65 80339 München Deutschland
<b>MDR Certificate No.</b>	G20 090341 0017 Rev. 00
<b>Valid until</b>	2028-11-01

### Attachment to EU Declaration of Conformity

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
<b>576818</b>	<b>Preference 6er</b>	<b>Class IIa</b>	<b>Rule 19, bullet 3</b>
000578264	Preference 6er O310+ A1	Class IIa	Rule 19, bullet 3
000578265	Preference 6er O310+ A2	Class IIa	Rule 19, bullet 3
000578266	Preference 6er O310+ A3	Class IIa	Rule 19, bullet 3
000578267	Preference 6er O310+ A3.5	Class IIa	Rule 19, bullet 3
000578268	Preference 6er O310+ A4	Class IIa	Rule 19, bullet 3
000578269	Preference 6er O310+ B1	Class IIa	Rule 19, bullet 3
000578270	Preference 6er O310+ B2	Class IIa	Rule 19, bullet 3
000578271	Preference 6er O310+ B3	Class IIa	Rule 19, bullet 3
000578272	Preference 6er O310+ B4	Class IIa	Rule 19, bullet 3
000578273	Preference 6er O310+ C1	Class IIa	Rule 19, bullet 3
000578274	Preference 6er O310+ C2	Class IIa	Rule 19, bullet 3
000578275	Preference 6er O310+ C3	Class IIa	Rule 19, bullet 3
000578276	Preference 6er O310+ C4	Class IIa	Rule 19, bullet 3
000578277	Preference 6er O310+ D2	Class IIa	Rule 19, bullet 3
000578278	Preference 6er O310+ D3	Class IIa	Rule 19, bullet 3
000578279	Preference 6er O310+ D4	Class IIa	Rule 19, bullet 3
000578282	Preference 6er O320+ A1	Class IIa	Rule 19, bullet 3
000578283	Preference 6er O320+ A2	Class IIa	Rule 19, bullet 3
000578284	Preference 6er O320+ A3	Class IIa	Rule 19, bullet 3
000578285	Preference 6er O320+ A3.5	Class IIa	Rule 19, bullet 3
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000578287	Preference 6er O320+ B1	Class IIa	Rule 19, bullet 3
000578288	Preference 6er O320+ B2	Class IIa	Rule 19, bullet 3
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000578292	Preference 6er O320+ C2	Class IIa	Rule 19, bullet 3
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000578301	Preference 6er O330+ A2	Class IIa	Rule 19, bullet 3
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000578585	Preference 6er U140- D4	Class IIa	Rule 19, bullet 3
000578588	Preference 6er U150- A1	Class IIa	Rule 19, bullet 3
000578589	Preference 6er U150- A2	Class IIa	Rule 19, bullet 3
000578590	Preference 6er U150- A3	Class IIa	Rule 19, bullet 3
000578591	Preference 6er U150- A3.5	Class IIa	Rule 19, bullet 3



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000578593	Preference 6er U150- B1	Class IIa	Rule 19, bullet 3
000578594	Preference 6er U150- B2	Class IIa	Rule 19, bullet 3
000578595	Preference 6er U150- B3	Class IIa	Rule 19, bullet 3
000578596	Preference 6er U150- B4	Class IIa	Rule 19, bullet 3
000578597	Preference 6er U150- C1	Class IIa	Rule 19, bullet 3
000578598	Preference 6er U150- C2	Class IIa	Rule 19, bullet 3
000578599	Preference 6er U150- C3	Class IIa	Rule 19, bullet 3
000578600	Preference 6er U150- C4	Class IIa	Rule 19, bullet 3
000578601	Preference 6er U150- D2	Class IIa	Rule 19, bullet 3
000578602	Preference 6er U150- D3	Class IIa	Rule 19, bullet 3
000578603	Preference 6er U150- D4	Class IIa	Rule 19, bullet 3
000578606	Preference 6er U160- A1	Class IIa	Rule 19, bullet 3
000578607	Preference 6er U160- A2	Class IIa	Rule 19, bullet 3
000578608	Preference 6er U160- A3	Class IIa	Rule 19, bullet 3
000578609	Preference 6er U160- A3.5	Class IIa	Rule 19, bullet 3
000578610	Preference 6er U160- A4	Class IIa	Rule 19, bullet 3
000578611	Preference 6er U160- B1	Class IIa	Rule 19, bullet 3
000578612	Preference 6er U160- B2	Class IIa	Rule 19, bullet 3
000578613	Preference 6er U160- B3	Class IIa	Rule 19, bullet 3
000578614	Preference 6er U160- B4	Class IIa	Rule 19, bullet 3
000578615	Preference 6er U160- C1	Class IIa	Rule 19, bullet 3
000578616	Preference 6er U160- C2	Class IIa	Rule 19, bullet 3
000578617	Preference 6er U160- C3	Class IIa	Rule 19, bullet 3
000578618	Preference 6er U160- C4	Class IIa	Rule 19, bullet 3
000578619	Preference 6er U160- D2	Class IIa	Rule 19, bullet 3
000578620	Preference 6er U160- D3	Class IIa	Rule 19, bullet 3
000578621	Preference 6er U160- D4	Class IIa	Rule 19, bullet 3
000605110	Preference 6er O010+ BL2	Class IIa	Rule 19, bullet 3
000605111	Preference 6er O020+ BL2	Class IIa	Rule 19, bullet 3
000605112	Preference 6er O030+ BL2	Class IIa	Rule 19, bullet 3
000605113	Preference 6er O040+ BL2	Class IIa	Rule 19, bullet 3
000605114	Preference 6er O050+ BL2	Class IIa	Rule 19, bullet 3
000605115	Preference 6er O310+ BL2	Class IIa	Rule 19, bullet 3
000605116	Preference 6er O320+ BL2	Class IIa	Rule 19, bullet 3
000605117	Preference 6er O330+ BL2	Class IIa	Rule 19, bullet 3
000605118	Preference 6er O340+ BL2	Class IIa	Rule 19, bullet 3
000605119	Preference 6er O350+ BL2	Class IIa	Rule 19, bullet 3
000605120	Preference 6er O410+ BL2	Class IIa	Rule 19, bullet 3
000605121	Preference 6er O420+ BL2	Class IIa	Rule 19, bullet 3
000605122	Preference 6er O430+ BL2	Class IIa	Rule 19, bullet 3
000605123	Preference 6er O440+ BL2	Class IIa	Rule 19, bullet 3
000605124	Preference 6er O450+ BL2	Class IIa	Rule 19, bullet 3
000605125	Preference 6er U110- BL2	Class IIa	Rule 19, bullet 3
000605126	Preference 6er U130- BL2	Class IIa	Rule 19, bullet 3
000605127	Preference 6er U140- BL2	Class IIa	Rule 19, bullet 3
000605128	Preference 6er U150- BL2	Class IIa	Rule 19, bullet 3
000605129	Preference 6er U160- BL2	Class IIa	Rule 19, bullet 3
000605130	Preference 6er O010+ BL4	Class IIa	Rule 19, bullet 3
000605131	Preference 6er O020+ BL4	Class IIa	Rule 19, bullet 3



000605132	Preference 6er O030+ BL4	Class IIa	Rule 19, bullet 3
000605133	Preference 6er O040+ BL4	Class IIa	Rule 19, bullet 3
000605134	Preference 6er O050+ BL4	Class IIa	Rule 19, bullet 3
000605135	Preference 6er O310+ BL4	Class IIa	Rule 19, bullet 3
000605136	Preference 6er O320+ BL4	Class IIa	Rule 19, bullet 3
000605137	Preference 6er O330+ BL4	Class IIa	Rule 19, bullet 3
000605138	Preference 6er O340+ BL4	Class IIa	Rule 19, bullet 3
000605139	Preference 6er O350+ BL4	Class IIa	Rule 19, bullet 3
000605140	Preference 6er O410+ BL4	Class IIa	Rule 19, bullet 3
000605141	Preference 6er O420+ BL4	Class IIa	Rule 19, bullet 3
000605142	Preference 6er O430+ BL4	Class IIa	Rule 19, bullet 3
000605143	Preference 6er O440+ BL4	Class IIa	Rule 19, bullet 3
000605144	Preference 6er O450+ BL4	Class IIa	Rule 19, bullet 3
000605145	Preference 6er U110- BL4	Class IIa	Rule 19, bullet 3
000605146	Preference 6er U130- BL4	Class IIa	Rule 19, bullet 3
000605147	Preference 6er U140- BL4	Class IIa	Rule 19, bullet 3
000605148	Preference 6er U150- BL4	Class IIa	Rule 19, bullet 3
000605149	Preference 6er U160- BL4	Class IIa	Rule 19, bullet 3
<b>576697</b>	<b>Preference 8er</b>	<b>Class IIa</b>	<b>Rule 19, bullet 3</b>
000578624	Preference 8er O800+ A1	Class IIa	Rule 19, bullet 3
000578625	Preference 8er O800+ A2	Class IIa	Rule 19, bullet 3
000578626	Preference 8er O800+ A3	Class IIa	Rule 19, bullet 3
000578627	Preference 8er O800+ A3.5	Class IIa	Rule 19, bullet 3
000578628	Preference 8er O800+ A4	Class IIa	Rule 19, bullet 3
000578629	Preference 8er O800+ B1	Class IIa	Rule 19, bullet 3
000578630	Preference 8er O800+ B2	Class IIa	Rule 19, bullet 3
000578631	Preference 8er O800+ B3	Class IIa	Rule 19, bullet 3
000578632	Preference 8er O800+ B4	Class IIa	Rule 19, bullet 3
000578633	Preference 8er O800+ C1	Class IIa	Rule 19, bullet 3
000578634	Preference 8er O800+ C2	Class IIa	Rule 19, bullet 3
000578635	Preference 8er O800+ C3	Class IIa	Rule 19, bullet 3
000578636	Preference 8er O800+ C4	Class IIa	Rule 19, bullet 3
000578637	Preference 8er O800+ D2	Class IIa	Rule 19, bullet 3
000578638	Preference 8er O800+ D3	Class IIa	Rule 19, bullet 3
000578639	Preference 8er O800+ D4	Class IIa	Rule 19, bullet 3
000578642	Preference 8er O840+ A1	Class IIa	Rule 19, bullet 3
000578643	Preference 8er O840+ A2	Class IIa	Rule 19, bullet 3
000578644	Preference 8er O840+ A3	Class IIa	Rule 19, bullet 3
000578645	Preference 8er O840+ A3.5	Class IIa	Rule 19, bullet 3
000578646	Preference 8er O840+ A4	Class IIa	Rule 19, bullet 3
000578647	Preference 8er O840+ B1	Class IIa	Rule 19, bullet 3
000578648	Preference 8er O840+ B2	Class IIa	Rule 19, bullet 3
000578649	Preference 8er O840+ B3	Class IIa	Rule 19, bullet 3
000578650	Preference 8er O840+ B4	Class IIa	Rule 19, bullet 3
000578651	Preference 8er O840+ C1	Class IIa	Rule 19, bullet 3
000578652	Preference 8er O840+ C2	Class IIa	Rule 19, bullet 3
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000578654	Preference 8er O840+ C4	Class IIa	Rule 19, bullet 3
000578655	Preference 8er O840+ D2	Class IIa	Rule 19, bullet 3
000578656	Preference 8er O840+ D3	Class IIa	Rule 19, bullet 3

000578657	Preference 8er O840+ D4	Class IIa	Rule 19, bullet 3
000578660	Preference 8er O880+ A1	Class IIa	Rule 19, bullet 3
000578661	Preference 8er O880+ A2	Class IIa	Rule 19, bullet 3
000578662	Preference 8er O880+ A3	Class IIa	Rule 19, bullet 3
000578663	Preference 8er O880+ A3.5	Class IIa	Rule 19, bullet 3
000578664	Preference 8er O880+ A4	Class IIa	Rule 19, bullet 3
000578665	Preference 8er O880+ B1	Class IIa	Rule 19, bullet 3
000578666	Preference 8er O880+ B2	Class IIa	Rule 19, bullet 3
000578667	Preference 8er O880+ B3	Class IIa	Rule 19, bullet 3
000578668	Preference 8er O880+ B4	Class IIa	Rule 19, bullet 3
000578669	Preference 8er O880+ C1	Class IIa	Rule 19, bullet 3
000578670	Preference 8er O880+ C2	Class IIa	Rule 19, bullet 3
000578671	Preference 8er O880+ C3	Class IIa	Rule 19, bullet 3
000578672	Preference 8er O880+ C4	Class IIa	Rule 19, bullet 3
000578673	Preference 8er O880+ D2	Class IIa	Rule 19, bullet 3
000578674	Preference 8er O880+ D3	Class IIa	Rule 19, bullet 3
000578675	Preference 8er O880+ D4	Class IIa	Rule 19, bullet 3
000578678	Preference 8er U800- A1	Class IIa	Rule 19, bullet 3
000578679	Preference 8er U800- A2	Class IIa	Rule 19, bullet 3
000578680	Preference 8er U800- A3	Class IIa	Rule 19, bullet 3
000578681	Preference 8er U800- A3.5	Class IIa	Rule 19, bullet 3
000578682	Preference 8er U800- A4	Class IIa	Rule 19, bullet 3
000578683	Preference 8er U800- B1	Class IIa	Rule 19, bullet 3
000578684	Preference 8er U800- B2	Class IIa	Rule 19, bullet 3
000578685	Preference 8er U800- B3	Class IIa	Rule 19, bullet 3
000578686	Preference 8er U800- B4	Class IIa	Rule 19, bullet 3
000578687	Preference 8er U800- C1	Class IIa	Rule 19, bullet 3
000578688	Preference 8er U800- C2	Class IIa	Rule 19, bullet 3
000578689	Preference 8er U800- C3	Class IIa	Rule 19, bullet 3
000578690	Preference 8er U800- C4	Class IIa	Rule 19, bullet 3
000578691	Preference 8er U800- D2	Class IIa	Rule 19, bullet 3
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000578693	Preference 8er U800- D4	Class IIa	Rule 19, bullet 3
000578697	Preference 8er U840- A1	Class IIa	Rule 19, bullet 3
000578698	Preference 8er U840- A2	Class IIa	Rule 19, bullet 3
000578699	Preference 8er U840- A3	Class IIa	Rule 19, bullet 3
000578700	Preference 8er U840- A3.5	Class IIa	Rule 19, bullet 3
000578701	Preference 8er U840- A4	Class IIa	Rule 19, bullet 3
000578702	Preference 8er U840- B1	Class IIa	Rule 19, bullet 3
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000578704	Preference 8er U840- B3	Class IIa	Rule 19, bullet 3
000578705	Preference 8er U840- B4	Class IIa	Rule 19, bullet 3
000578706	Preference 8er U840- C1	Class IIa	Rule 19, bullet 3
000578707	Preference 8er U840- C2	Class IIa	Rule 19, bullet 3
000578708	Preference 8er U840- C3	Class IIa	Rule 19, bullet 3
000578709	Preference 8er U840- C4	Class IIa	Rule 19, bullet 3
000578710	Preference 8er U840- D2	Class IIa	Rule 19, bullet 3
000578711	Preference 8er U840- D3	Class IIa	Rule 19, bullet 3
000578712	Preference 8er U840- D4	Class IIa	Rule 19, bullet 3
000578715	Preference 8er U880- A1	Class IIa	Rule 19, bullet 3

000578716	Preference 8er U880- A2	Class IIa	Rule 19, bullet 3
000578717	Preference 8er U880- A3	Class IIa	Rule 19, bullet 3
000578718	Preference 8er U880- A3.5	Class IIa	Rule 19, bullet 3
000578719	Preference 8er U880- A4	Class IIa	Rule 19, bullet 3
000578720	Preference 8er U880- B1	Class IIa	Rule 19, bullet 3
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000578722	Preference 8er U880- B3	Class IIa	Rule 19, bullet 3
000578723	Preference 8er U880- B4	Class IIa	Rule 19, bullet 3
000578724	Preference 8er U880- C1	Class IIa	Rule 19, bullet 3
000578725	Preference 8er U880- C2	Class IIa	Rule 19, bullet 3
000578726	Preference 8er U880- C3	Class IIa	Rule 19, bullet 3
000578727	Preference 8er U880- C4	Class IIa	Rule 19, bullet 3
000578728	Preference 8er U880- D2	Class IIa	Rule 19, bullet 3
000578729	Preference 8er U880- D3	Class IIa	Rule 19, bullet 3
000578730	Preference 8er U880- D4	Class IIa	Rule 19, bullet 3
000605150	Preference 8er O800+ BL2	Class IIa	Rule 19, bullet 3
000605151	Preference 8er O840+ BL2	Class IIa	Rule 19, bullet 3
000605152	Preference 8er O880+ BL2	Class IIa	Rule 19, bullet 3
000605153	Preference 8er U800- BL2	Class IIa	Rule 19, bullet 3
000605154	Preference 8er U840- BL2	Class IIa	Rule 19, bullet 3
000605155	Preference 8er U880- BL2	Class IIa	Rule 19, bullet 3
000605156	Preference 8er O800+ BL4	Class IIa	Rule 19, bullet 3
000605157	Preference 8er O840+ BL4	Class IIa	Rule 19, bullet 3
000605158	Preference 8er O880+ BL4	Class IIa	Rule 19, bullet 3
000605159	Preference 8er U800- BL4	Class IIa	Rule 19, bullet 3
000605160	Preference 8er U840- BL4	Class IIa	Rule 19, bullet 3
000605161	Preference 8er U880- BL4	Class IIa	Rule 19, bullet 3

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Revision History			
Version	Date	Author	Remark
1.0	2024-05-15	Miriam Stange	First MDR Version