

## Certificate of Biocompatibility

### Test material: IvoBase® Denture Base Material

<b>Manufacturer</b>	Ivoclar Vivadent AG, Bendererstrasse 2, 9494 Schaan, Liechtenstein	
<b>Standard composition</b>	IvoBase Hybrid IvoBase High Impact	Polymethyl methacrylate with a cross-linked monomer matrix Impact resistant-modified polymethyl methacrylate with a cross-linked monomer matrix Shrinkage-compensating injection procedure (IvoBase Injector) with directed temperature control.
<b>Classification</b>	IvoBase denture base materials comply with the ISO 20795-1:2008 standard and, given their chemical composition and polymerization temperature, belong to the auto-curing polymers (Type 2, Class 1).	
<b>Residual monomer content</b>	The high monomer conversion during the standard polymerization process results in a very low initial residual monomer content for auto-curing polymers. Testing according to ISO 20795-1:2008,	
	Limit	for auto-curing polymers 4.5 percent for heat-curing polymers 2.2 percent
	Value achieved	by IvoBase < 1.5 percent
	This content can be further reduced to below 1 percent with the RMR function (residual monomer content) of the IvoBase Injector.	
<b>Water solubility</b>	Testing according to ISO 20795-1:2008	
	Limit for auto-curing polymers	$\mu\text{g}/\text{mm}^3 < 8.0$
	Limit for heat-curing polymers	$\mu\text{g}/\text{mm}^3 < 1.6$
	Example value for IvoBase Hybrid	$\mu\text{g}/\text{mm}^3 < 0.1$
	Example value for IvoBase High Impact	$\mu\text{g}/\text{mm}^3 < 0.1$
<b>Surface quality</b>	The surface quality is an important prerequisite for denture hygiene. The basal gloss in IvoBase dentures suggests high resistance to micro-organisms. <b>Test:</b> Examining the colonization with <i>Candida albicans</i> (yeast). <b>Result:</b> IvoBase materials show low colonization with <i>C. albicans</i> . <b>Test institute:</b> State University of New York at Buffalo, Carlos Muñoz-Viveros	
<b>Cytotoxicity</b>	Cytotoxicity tests were conducted on cells of the mouse cell line L929 with extracts of IvoBase Hybrid and IvoBase High Impact. The extracts did not reveal any cytotoxic effect .	
<b>Genotoxicity</b>	The AMES reversion mutation test was conducted on bacterial cells with extracts of IvoBase Hybrid and IvoBase Hybrid. The extracts did not show any mutagenic effects .	

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