AESTHETIC RED / AESTHETIC BLUE

Certificate of Biocompatibility

Test material: AESTHETIC RED AND AESTHETIC BLUE Denture Base Material

Manufacturer	CANDULOR AG, Boulevard Lilienthal 8, CH-8152 Glattpark (Opfikon), Switzerland	
Standard composition	AESTHETIC RED	Heat-curing denture basematerial Polymethyl methacrylate with a cross-linked monomer matrix
	AESTHEIC BLUE	Auto-curing denture basematerial Polymethyl methacrylate with a cross-linked monomer matrix
Classification	AESTHETIC RED denture base materials comply with the ISO 20795-1:2013 standard and, given their chemical composition and polymerization temperature, belong to the heat-curing polymers (Type 1, Class 1). AESTHETIC BLUE denture base materials comply with the ISO 20795-1:2013 standard and, given their chemical composition and polymerization temperature, belong to the auto-curing polymers (Type 2, Class 1).	
Residual monomer content	testing according to ISO 20795-1:2013	
	Limit for auto-curing polymers	4.5 percent
	Limit for heat-curing polymers	2.2 percent
	Value achieved by AESTHETIC RED	≤ 2.2 percent
	Value achieved by AESTHETIC BLUE	≤ 4.5 percent
Water solubility	testing according to ISO 20795-1:2013	
	Limit for auto-curing polymers	$\mu g/mm^3 < 8.0$
	Limit for heat-curing polymers	$\mu g/mm^3 < 1.6$
	Example value for AESTHETIC RED	$0.1 \mu g/mm^3$
	Example value for AESTHETIC BLUE	$2.7 \mu g/mm^3$
Cytotoxicity	Results: Polymerized denture base material was extracted with culture media for 24 h at 37 °C and the resulting elute was tested in an in vitro cytotoxicity test (XTT). No cytotoxicity could be detected.	
Genotoxicity	Results: Polymerized denture base material was extracted and the resulting eluate was tested. In both test systems no genotoxicity could be detected.	

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