

DECLARATION OF CONFORMITY

JELENKO

located at
5855 Oberlin Drive San Diego, CA , 92121-4718
declares, under our sole responsibility,
The Following Dental Alloy Product:

JEL BIOS-10

Complies with the legislation of
ISO 13485 - Medical Devices - Particular requirements for the application of ISO 9001;
Following the Provisions of
93/42/EEC; Annex II - Council of European Communities Directive Concerning
Medical Devices.

Manufacturer

JELENKO
5855 Oberlin Drive
San Diego, CA 92121-4718

EC Representative

Medical Device Safety Service Gmbh,
Schiffgraben 41, D-30175
Hannover,Germany

Issued By:

Craig Jolicoeur
Quality and Regulatory Assurance Manager

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