

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**

**** This document is generated electronically and does not require a signature ****

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