

## Memo

To:

To whom it may concern

From:

Quality Assurance

CC:

Date:

August 30, 2010

Subject:

Elephant dental Quality Control

Herewith we, Elephant Dental, declare that our Dental Alloys are produced according to the highest quality standards and that the properties and composition of the delivered product is fully conform our product specifications.

The Elephant Dental alloys fulfill the council directive 93/42EEC requirements for medical devices and the ISO 22674:2006 requirements for dental metallic materials and have proven themselves over more than 30 years.

The Elephant alloys are produced from raw material with a purity of 99.9 to 99.9999% depending on the element. Each lot of raw material is analyzed for unwanted trace elements, such as Pb (lead), Be (Beryllium), Ni (Nickel) and Cd (Cadmium). Suppliers of raw materials are selected on the capability of supplying the highest purity of raw materials and even the base materials like gold are analyzed.

The production processes are certified, according to the ISO 13485:2003 standard, "Quality Management systems for Medical Devices" and fulfill the FDA GMP requirements.

After the production each batch is analyzed for homogeneity, correct composition and impurities, assuring reproducible high quality dental restorations.

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