

DECLARATION OF CYTOCOMPATIBILITY

ALLOY TESTED:

PAL KERAMIT LF

Unisersal alloy with 40.0% of gold and platinum group metals

Chemical composition:

Pd 39,8 - Ag 51,8 - In 2,1 - Zn 4,0 - Sn 2,1 - Ru x

% (m/m) Determined by Emission Spectrometric Analysis.

Manufacturer:

NOBIL METAL Spa

Strada San Rocco, 28 - 14018 Villafranca d'Asti (AT) - Italia

I declare that cytotoxicity properties of **PAL KERAMIT LF** were evaluated according to International Standard ISO 10993-5 Biological Evaluation of Medical Devices- Part 5, Tests for cytotoxicity: in vitro methods.

In particular, the alloy samples were tested with L929 mouse fibroblasts in a direct cell contact assay.

Microscopic examination, vital staining and MTT test at the end of the incubation time were performed in order to establish cytotoxic effects, in comparison with negative (Tissue Culture Polystyrene) and positive (Cu-Ni-Al alloy) control samples. Tests were performed on six samples produced by the lost wax technique according to manufacturer directions.

Results for PAL KERAMIT LF cytotoxicity tests were always similar to those obtained for negative control samples.

PAL KERAMIT LF EXHIBITED NO CYTOTOXIC ACTIVITY.

NOBIL BIO RICERCHE s.r.l.

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