

DECLARATION OF CYTOCOMPATIBILITY

ALLOY TESTED:

KERAMIT 150

Porcelain fused to metal alloy with 67.5% of gold and platinum group metals

Chemical composition:

Au 15,0 - Pd 52,2 - Ag 20,2 - In 6,0 - Sn 5,3 - Ga 1,0 - 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 **KERAMIT 150** 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 sintering technique according to manufacturer directions.

Results for KERAMIT 150 cytotoxicity tests were always similar to those obtained for negative control samples.

KERAMIT 150 EXHIBITED NO CYTOTOXIC ACTIVITY

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