

DECLARATION OF CYTOTOXICITY

ALLOY TESTED:

NOBIL 4000

Porcelain fused to metal Cobalt-based alloy

Chemical composition:

Cr 31,0 - Co 62,0 - Mo 4,0 - Si 2,2 - Mn x - Fe x - W 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 **NOBIL 4000** 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 NOBIL 4000 cytotoxicity tests were always similar to those obtained for negative control samples.

NOBIL 4000 EXHIBITED NO CYTOTOXIC ACTIVITY

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March, 2004