

DECLARATION OF CYTOCOMPATIBILITY

ALLOY TESTED:

UNISOLDER

Dental brazing alloy with 42.0% of gold and platinum group metals

Chemical composition:

Au 42,0 - Ag 38,5 - In 8,5 - Zn 11,0

% (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 **UNISOLDER** 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 UNISOLDER cytotoxicity showed light cytotoxicity.

UNISOLDER EXHIBITED LIGHT CYTOTOXIC ACTIVITY.

NOBIL BIO RICERCHE s.r.l.

Strada San Rocco, 36
14018 Villafranca d'Asti
Italia

Dr.ssa Clara Cassinelli

Clara Cassinelli
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