

Final Report SAM2817i

**BIOLOGICAL REACTIVITY IN VITRO
CYTOTOXICITY - ELUTION TEST**

Study Program: SAM2817

Contract n.: E05/0137.4MI

Sponsor: ANDROMEDICAL S.L.
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Test substance: ANDRO-PENIS

Study Director
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CONCLUSIONS

On the basis of the results, interpreted according to ISO 10993-5:1999, the test material PLASTIC (1 and 13) can be considered **NON CYTOTOXIC**.

On the basis of the results, interpreted according to ISO 10993-5:1999, the test material FOAM (15) can be considered **NON CYTOTOXIC**.

On the basis of the results, interpreted according to ISO 10993-5:1999, the test material ALLUMINUM ALLOY (9-12) can be considered **NON CYTOTOXIC**.

On the basis of the results, interpreted according to ISO 10993-5:1999, the test material SILICON (14) can be considered **NON CYTOTOXIC**.

On the basis of the results, interpreted according to ISO 10993-5:1999 and USP 28, the metal bar of ANDROPENIS GOLD can be considered **MILDLY CYTOTOXIC** and complies with USP 28 requirements for cytotoxicity of medical devices.

On the basis of the results, interpreted according to ISO 10993-5:1999 and USP 28, the test substance ANDRORING can be considered **NON CYTOTOXIC**.