

To protect the privacy of customers or suppliers of Salamander Jewelry. We erased their address from this document.

# BIOFLEX

## STATEMENT ON COMPLIANCE TO REGULATIONS ON MEDICAL USE

We confirm that the material used in the fabrication of BioFlex products in its pure form (without additives) fulfils the requirements on materials used for articles or components of articles intended for medical use as described in:

**Council of Europe** European Pharmacopoeia, 5<sup>th</sup> edition(2004), and supplement 5.4 (04/2006) Monograph 3.2.2.

**USA** The product has passed the Class VI tests (Bio-compatibility) of the United States Pharmacopoeia XXIV and has been assigned a FDA Drug Master File.

**Additional Information:** The material has successfully passed the biological tests according to ISO 10993 –

### Disclaimer

The information contained herein is to our knowledge accurate and reliable as of the date of publication. It is the customer's responsibility to inspect and test our products in order to satisfy himself as to the suitability of the products for the customer's particular purpose. The customer is also responsible for the appropriate, safe and legal use, processing and handling of our products. [REDACTED] shall not be under a duty to notify you of any changes to the regulations.

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