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# 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.

Insofar as products supplied by [REDACTED] or its subsidiary companies are used in conjunction with third party materials, it is the responsibility of the customer to obtain all necessary information relating to the third party materials and ensure that [REDACTED]'s products when used together with these materials are suitable for the customer's particular purpose. No liability can be accepted in respect of the use of [REDACTED]'s products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials.