Biocompatibility of PrimePart®/ PA 2200

USP Biological Test (Classification VI/121°C)

The organization USP (United States Pharmacopeia) establishes public standards to help assure good quality of medicines and medical products.
The USP Biological Tests evaluate biological reactivity of living tissues to polymers. Test items are raw polymeric material (e.g. powders) or semi-finished plastic products, but these tests are directly related to the intended end-use of the plastic articles.
Classification VI - Six classes of polymers are defined. This classification is based on a series of in vivo tests for which extracts, materials and routes of administration are specified. Class VI is the highest class with most extensive tests (type/number of extracts for injection, type/number of animals, ...). The temperature 121°C identifies that the extraxtion of the test item was carried out at this standard temperature.

Test-Methods and Evaluation of Test results

	Method	Evaluation of tissue reaction for
Systemic Injection Test	Single-dose injection of specific extracts into animal tissue	Convulsion, prostration, body weight loss, death, ...
Intracutaneous Test		erythema, eschar, edemal, ...
Implantation Test	Implantation of material into animal tissue	hemorrhage, necrosis, discoloration, infections, encapsulation, ...

For detailed information and test reports in detail please contact GES.

Consequences of Positive Certification

In all tests no significant signs and reactions of animals were detected.

So, PrimePart® / PA 2200 meets all the criteria of the USP-Biological Test Class VI/121°C.

The materials fulfil requirements for end-use-applications in medical products.

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