DSM Somos

DSM Somos WaterShed® XC 11122 and ProtoGen™ 18420 have passed ISO 10993 biocompatibility testing. This is a major accomplishment, given this ISO test is considered to be more stringent and more widely accepted within the medical device community worldwide than even USP Class VI. Below, we have provided you with some details about the ISO 10993 certification. Please familiarize yourselves with the information, as you may be asked about it by your customers. If you have any questions, as always, please contact us directly.

About the ISO 10993 Standards:

Materials characterization forms the basis for understanding the composition of a medical device material. It also serves as a means to ensure standardization of materials from one lot of devices to the next. As the harmonization of ISO 10993 standards and FDA requirements proceeds, the methods described is used by the U.S. device industry to a greater and greater extent to aid in the selection of optimal materials and to control the uniformity of medical products.

The biological evaluation of medical devices is currently governed by the set of standards developed by the International Organization for Standardization (ISO) and known as ISO 10993 or, in the United States, by FDA blue book memorandum #G95-1, which is a modification of ISO 10993-1, "Guidance on Selection of Tests." ISO 10993-1 states that "in the selection of materials to be used in device manufacture, the first consideration should be fitness for purpose having regard to the characteristics and properties of the material, which include chemical, toxicological, physical, electrical, morphological, and mechanical properties." Characterization of medical device materials is thus clearly identified as one of the first steps in their overall evaluation.

1) ISO 10993-5: Cytotoxicity Test - L929 MEM Elution

Description: The "in-vitro" biological reactivity of the L929 mouse fibroblast cell culture is determined in response to an extract of the test material in triplicate. The cells are allowed to grow to sub-confluency in tissue culture plates. An extract of the test material is prepared in Minimum Essential Media (MEM), which is transferred onto the cell layer. The plates are incubated for forty-eight hours at 37°C in a 5% Co2 incubator, and scored for reactivity at twenty-four and forty-eight hours on a scale from Grade 0 (no reactivity) to Grade 4 (severe reactivity). The test item is considered non-cytotoxic if none of the cultures exposed to the test item shows greater than mild reactivity (Grade 2).

2) ISO 10993–10: Sensitization Test

The Kligman Maximization Test evaluates the allergenic potential or sensitizing capacity of the test article in guinea pigs. The test article will be exposed to the test system directly or through test article extracts. Extracts of the test material are prepared in a polar (saline) and/or non-polar (cotton seed oil) solution. The test begins with intradermal injections of Freund's Complete Adjuvant (FCA) and the test article. Seven days later the injection sites are covered with the test article/extract for a period of forty-eight hours. Fourteen days later a new site is challenged with a topical application of the test article/extract and scored at forty-eight hours. A sensitization reaction to the test article is scored based on the defined evaluation criteria in ISO 10993-10.

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3) ISO 10993–10: Irritation Test

The Intracutaneous Injection Test is designed to evaluate local responses to solutions or extracts following intracutaneous injections into rabbits. The test article will be exposed to the test system directly or through test article extracts. Extracts of the test material are prepared in a polar (saline) and/or non-polar (cotton seed oil) solution. A minimum of two rabbits are injected intracutaneously with the test article and control materials. The injected sites are examined over a seventy-two hour period for evidence of tissue reaction such as erythema, edema, and necrosis. Observations are scored according to the Classification System for Scoring Skin Reactions (Draize scale). At the end of the observation period the scores are used to determine an overall mean reaction score for the test article versus the corresponding control article. The requirements of the test are met if the difference of the mean reaction score for the test article and the control article is 1.0 or less.

Levels of Biocompatibility

Medical Device Manufacturers characterize/qualify materials and devices by Levels of Biocompatibility. They will refer to them as Level 1, Level 2 and Level 3. **You might be asked the question (especially at the NPE) by a medical device company: what level of testing did DSM Somos pass for ISO 10993? The answer is Level 1 (Cytotoxicity, Sensitization and Irritation).** Below is a description of the various Levels:

Level 1 tests provide the device manufacturer information on the physical, chemical and toxicological characterization of the materials being considered for use in their medical device or prototype. These tests are considered the **initial** characterization of biomaterials and serve as the **foundation** for all other testing conducted for their medical device/prototype. Materials that pass have broad applications. These materials are characterized as “recommended for use” during the early stages of medical device development.

Level 2 tests are acute toxicity tests and some subchronic and chronic testing (special testing due to complexity and/or intended use of the device). Simply put, it is an extension of Level 1 with additional in-vitro and in-vivo testing of devices. A Level 1 study should be completed prior to conducting all level 2 testing.

Level 3 testing is the highest level of testing for a medical device and involves clinical studies. This is especially important for implantable devices.

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Have questions regarding ISO 10993 certification for DSM Somos stereolithography materials?

Please contact: Christine Woollard
847-608-2596
christine.woollard@dsm.com