

FAQs: DSM Somos Medical-Grade Materials

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 FAQs which will help you communicate about these materials to your customers. Please familiarize yourselves with the information and, if you have any questions, as always, please contact us directly.

Q: Are Somos[®] medical-grade materials FDA approved?

A: No. Somos ProtoGen[™] 18420 and WaterShed[®] XC stereolithography materials are not FDA approved. They meet ISO 10993-5: Cytotoxicity, ISO10993-10: Sensitization, ISO 10993-10: Irritation, and USP Class VI standards.

Q: Are there special handling/post-processing procedures that need to be followed in order to supply parts that meet medical approvals?

A: Yes. For more information please contact your DSM Somos sales representative http://www.dsmsomos.info/pages/contact_us/en/map.htm

Q: What is USP Class VI?

A: The USP Class tests are designed to determine the biological response of animals to direct and/or indirect contact with the test material. For more information please visit US Pharmacopoeia's website.

Q: What is ISO 10993?

A: Cytotoxicity Tests - ISO 10993-5 is a Cytotoxicity in-vitro screening test used to assess, in a fast and sensitive way, the biocompatibility of the test material when in contact with a specific cell culture.

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FAQs, cont'd

Q: What is ISO 10993? (cont'd)

A: Sensitization Tests - ISO 10993-10 is a sensitization test used to determine the allergic or sensitizing capacity to the repeated or prolonged exposure of a test material. Sensitization is characterized by the fact that reactions are delayed, not localized, and independent of dose.

Irritation Tests - ISO 10993-10 is an in-vivo irritation test to evaluate the potential for test materials, or their extracts, to cause irritation on an exposed part of the body. Standard studies are single exposure evaluations.

For more information please visit ISO's website.

Q: Other SL resin suppliers claim to offer medical-grade resins, so how can DSM Somos be the first to meet ISO medical standards?

A: DSM Somos is the first SL resin supplier to actually have ISO 10993 testing conducted on its materials and to subsequently pass those tests and receive full certifications. To view or receive copies of the ISO certificates for Somos medical-grade materials, please contact your DSM Somos sales representative.

Q: Does this mean that prototypes made with the above-specified DSM Somos resins are:

- **suitable for extended skin contact (i.e. hearing aids)?** Yes. Please contact your DSM Somos sales representative for more information.
- **able to be used for applications that will include contact with body fluids?** Please contact your DSM Somos sales representative for more information.
- **implantable?** No. It is important to note that DSM Somos medical-grade materials with ISO 10993-5 and ISO 10993-10 certification **cannot** be used to create implantable devices.

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FAQs, cont'd

Q: Can DSM Somos medical-grade materials be used to create end-use medical devices?

A: DSM Somos medical-grade materials can be used to create **SOME** medical devices (please contact your DSM Somos sales representative for details), however **additional medical testing is required** by regional and international regulatory departments.

Most medical device manufacturers, after the final device is created, are required to apply for additional regulatory certifications **for the device** based on what it is designed to do.

Q: What sterilization techniques can be used for prototypes made from DSM Somos medical-grade materials?

A: Products made from Somos medical-grade materials can be sterilized using common sterilization techniques. For more details on recommended sterilization methods, please contact your DSM Somos sales representative http://www.dsmsomos.info/pages/contact_us/en/map.htm

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Have more questions regarding DSM Somos medical-grade stereolithography materials?

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