

# DSM Press Release

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## **DSM Somos Brings Speed, Efficiency to Medical Device Prototyping with First Stereolithography Resins to Meet ISO 10993-5 and ISO 10993-10 Medical Standards**

DSM Somos, a leading global innovator in the development of high-performance stereolithography (SL) resins, announced today that two of their best selling materials, WaterShed<sup>®</sup> XC 11122 and ProtoGen<sup>™</sup> 18420, have become the only currently available SL resins to meet ISO 10933 standards for use in medical device applications. The announcement came after WaterShed<sup>®</sup> XC 11122, a clear, water-resistant SL resin and ProtoGen<sup>™</sup> 18420, a white, ABS-like General purpose resin, received ISO 10993-5 Cytotoxicity, ISO 10993-10 Sensitization and ISO 10993-10 Irritation certifications.

The new ISO certifications underscore the continued growth of DSM Somos as a leading provider of innovative additive fabrication materials for Life Sciences applications.

*"Passing ISO 10993 testing reflects DSM Somos' commitment to meeting the medical devices industry's demanding quality standards related to biocompatibility," says DSM Somos Marketing Manager Vince Adams. "This ISO certification also demonstrates that use of WaterShed<sup>®</sup> XC 11122 and ProtoGen<sup>™</sup> 18420 contributes to the ability of medical device developers to minimize product development risks and maximize their prototyping confidence."*

### **Implications for the Medical Device Industry**

In the 5,000+ companies throughout world that currently develop medical devices, success is all about speed—that is, the speed in which new and improved devices can be tried, tested, and introduced to the market.

Using traditional prototyping methods that most medical device companies are currently familiar with (such as micro-machining and vacuum casting), it can take several weeks or even months to create a new prototype.

*"Until now, medical device producers have been largely unfamiliar with stereolithography (SL) as a prototyping technology," says Adams, "which is not surprising, given that SL materials have, to this point, only been suitable for limited exposure to the human body and not qualified for biomedical applications. When we explain to these companies that they can now use SL to develop a prototype in a few days vs. 1-2 months, and that it's going to be functional, not fragile, they're pretty excited."*

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Watershed® XC 11122 and ProtoGen™ 18420 can now be recommended for use in medical device applications that include:

- Medical Device Prototypes
- Anatomical Modeling
- Investment Casting patterns (to produce implantable hip and knee joint replacements)
- Hearing Aide Device Manufacturing
- Surgical and Dental Drill Guides

#### **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.

#### **About DSM Somos**

DSM Somos is a leading global material suppliers to the rapid prototyping industry, providing stereolithography (SL) resins used for the creation of three-dimensional models and prototypes directly from digital data. Patented SOMOS® ProtoFunctional™ materials are used in a variety of industries, including automotive, aerospace, medical and telecommunications. SOMOS® SL resins provide advanced technology to respond to the changing needs of new product development and industrial design. These materials demonstrate a varying range of performance properties including: transparency, superior humidity and heat resistance, and mechanical properties which replicate those of many production grade plastics such as polypropylene, polyethylene, ABS and PBT. DSM Somos is an unincorporated subsidiary of DSM Desotech Inc. ([www.dsmdesotech.com](http://www.dsmdesotech.com)), and part of the global DSM family ([www.dsm.com](http://www.dsm.com)). More information may be found at: [www.dsmsomos.com](http://www.dsmsomos.com).

#### **About DSM Desotech**

DSM Desotech ([www.dsmdesotech.com](http://www.dsmdesotech.com)) is a world leader in the development of high performance UV-curable materials. For the telecommunications industry, Desotech is the leading global supplier of UV-curable coatings, inks and matrix materials for the production of glass optical fiber and optical cable. In the rapid prototyping industry, DSM Desotech's Somos® group is a leading innovator of UV-curable

stereolithography resins. In 2007 DSM Desotech launched its Uvention™ group, dedicated to the formulation of custom UV/EB curable coatings for a wide variety of industries seeking solutions for challenging performance requirements. In 2009 the company added two new business areas to its portfolio: UVolve® Instant Floor Coatings ([www.UVolveCoatings.com](http://www.UVolveCoatings.com)) and UVaCorr® anti-corrosion coatings for tube and pipe applications ([www.UVaCorr.com](http://www.UVaCorr.com)).

DSM Desotech is headquartered in Elgin, IL, USA, with facilities also located in Charlotte, NC, the Netherlands and China, as well as a joint venture in Japan. It is a business unit of DSM Resins and part of Royal DSM N.V. ([www.dsm.com](http://www.dsm.com)).

### **About DSM – the Life Sciences and Materials Sciences Company**

Royal DSM N.V. creates innovative products and services in Life Sciences and Materials Sciences that contribute to the quality of life. DSM's products and services are used globally in a wide range of markets and applications, supporting a healthier, more sustainable and more enjoyable way of life. End markets include human and animal nutrition and health, personal care, pharmaceuticals, automotive, coatings and paint, electrical and electronics, life protection and housing. DSM has annual net sales of EUR 9.3 billion and employs some 23,500 people worldwide. The company is headquartered in the Netherlands, with locations on five continents. DSM is listed on Euronext Amsterdam. More information: [www.dsm.com](http://www.dsm.com)

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### **Forward-looking statements**

This press release contains forward-looking statements. These statements are based on current expectations, estimates and projections of DSM management and information currently available to the company. The statements involve certain risks and uncertainties that are difficult to predict and therefore DSM does not guarantee that its expectations will be realized. Furthermore, DSM has no obligation to update the statements contained in this press release.

