

3D SYSTEMS CORPORATION
REGULATORY INFORMATION SHEET
VisiJet ® M2R-CL Plastic Material

ISO 10993 Biocompatibility Testing

VisiJet M2R-CL material printed in a ProJet 2500 has met the biocompatibility requirements of ISO 10993-5 Cytotoxicity, ISO 10993-10 Maximization and ISO 10993-10 Intracutaneous Reactivity. Based on these results, 3D Systems expects that similar articles made from this material will meet the compliance requirements of ISO 10993-5&10 when the produced parts are cleaned using the methods described in the attached Customer Information Bulletin.

It is the responsibility of each customer to independently determine that use of VisiJet M2R-CL material for their specific application is safe, lawful and technically suitable. Customers should conduct their own testing to ensure compliance with any specific requirements. 3D Systems recommends that customers re-verify material suitability for applications requiring USP Class VI compliance no less frequently than every two years from the date of this publication due to potential changes in the law, regulations, material formulation or manufacturing methods.

For additional information about VisiJet M2R-CL material, please contact your local sales representative.