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Biocompatibility of PostProcess Resin Removal Detergent per ISO 10993-1

Materials with applications which come in contact with the human body are held to a high regulatory standard. The evaluation of these materials falls under the guidance of ISO 10993-1: "Biological Evaluation of Medical Devices Part I: Evaluation and testing within a risk management process". Passing these standards is the first hurdle to having devices integrated into processes requiring human exposure.

Exposure evaluations per ISO 10993 for biocompatibility of medical devices were done on additively manufactured test articles that have undergone cleaning using PostProcess Technologies PLM-403-SUB resin removal detergent.

The applications for these materials to be evaluated are classified for limited and prolonged contact with intact skin, 0-30 days, per ISO 10993, as well as mucosal membrane for 24 hours. Exposure evaluations were conducted using biocompatible FormLabs Surgical Guide resin. Following printing, the test articles were cleaned using PostProcess resin removal detergent PLM-403-SUB. After cleaning, the test articles were evaluated for cytotoxicity, sensitization, and irritation per IOS 10933. Further evaluation for surface residue for allowable limits of leachable substances was completed per ISO 10993-17.

Results of evaluations for cytotoxicity, sensitization, and irritation (21-01218-G1, 21-01218-G2 and 21-01218-G4) did not elicit any positive response. Further evaluation of surface residue for allowable limits of leachable substances showed that at the highest detectable quantities of any constituent is at a level of 3 orders-of-magnitude lower than the minimum allowable exposure limit.

In conclusion, additively manufactured parts cleaned using PostProcess PLM-403-SUB comply with requirements for biocompatibility approval of medical devices per ISO 10993.

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