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1	31-01-07	-----	All pages	Initial Issue	-----
1A	21-04-07	485	Pages 1 & 6	Included Annexure II Performance qualification (PQ) for Part number (10-302 & 10-303).	Partial Issue
2	25-09-07	509	All Pages, Annexure – I & II	Revalidation only for second generation - 2023211001 (P/N: 10-0294) due to change in design & part numbers as per ECO # 215-1784. Removed OQ results of in Annexure – I & addressed in Annexure –III. Included Performance qualification (PQ) in Annexure II for Part number (10-0294).	Reissue

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The Regulatory Compliance Almanac Les Schnoll, 2008

Design Engineering Manual Mike Tooley, 2009-10-30 Design Engineering Manual offers a practical guide to the key principles of design engineering It features a compilation of extracts from several books within the range of Design Engineering books in the Elsevier collection The book is organized into 11 sections Beginning with a review of the processes of product development and design the book goes on to describe systematic ways of choosing materials and processes It details the properties of modern metallic alloys including commercial steels cast irons superalloys titanium alloys structural intermetallic compounds and aluminum alloys The book explains the human system interface procedures to assess the risks associated with job and task characteristics and environmental factors that may be encountered at work and affect behavior Product liability and safety rules are discussed The final section on design techniques introduces the design process from an inventors perspective to a more formal model called total design It also deals with the behavior of plastics that influence the application of practical and complex engineering equations and analysis in the design of products Provides a single source of critical information to the design engineer saving time and therefore money on a particular design project Presents both the fundamentals and advanced topics and also the latest information in key aspects of the design process Examines all aspects of the design process in one concise and accessible volume

Plastics in Medical Devices Vinny R. Sastri, 2013-11-27 Plastics in Medical Devices is a comprehensive overview of the main types of plastics used in medical device applications It focuses on the applications and properties that are most important in medical device design such as chemical resistance sterilization capability and biocompatibility The roles of additives stabilizers and fillers as well as the synthesis and production of polymers are covered

and backed up with a wealth of data tables Since the first edition the rate of advancement of materials technology has been constantly increasing In the new edition Dr Sastri not only provides a thorough update of the first edition chapters with new information regarding new plastic materials applications and new requirements but also adds two chapters one on market and regulatory aspects and supplier controls and one on process validation Both chapters meet an urgent need in the industry and make the book an all encompassing reference not found anywhere else Comprehensive coverage of uses of polymers for medical devices Unique coverage of medical device regulatory aspects supplier control and process validation Invaluable guide for engineers scientists and managers involved in the development and marketing of medical devices and materials for use in medical devices *Index of Specifications and Standards* , *Annual Technical Conference Transactions* American Society for Quality Control,American Society for Quality Control. Technical Conference,1966

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