GUJARAT TECHNOLOGICAL UNIVERSITY

Biomedical Engineering

M.E. Semester: II

Subject Name: **Medical Product Design: Standards & Regulation (Major Elective III)**

Sr. No.	Course Content
1.	Need of Standards and Regulations
2.	Medical Device Safety
3.	Quality Management
4.	Risk Management
5.	Device Risk and Quality Categorization
6.	Governmental Regulations of Medical Devices
7.	Standards
8.	Optimizing Use of Regulatory Resources
9.	Priorities in International Agendas
10.	Information Security
11.	Standardization and Regulatory concerns

Reference Books:

1. Medical device regulations: global overview and guiding principles
   -Michael Cheng, World Health Organization, 2003

2. Medical device quality assurance and regulatory compliance
   -Richard C. Fries Marcel Dekker, Inc., 1998

3. Medical Device Development: A Regulatory Overview
   -Jonathan S Kahan, Parexel International Corporation, 2000

4. Reliable design of medical devices
   -Richard C. Fries, CRC/Taylor & Francis, 2006

5. Handbook of medical device design
   -Richard C. Fries M. Dekker, 2001

6. The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices
   -Amiram Daniel, Ed Kimmelman, Kimberly A. Trautman ASQ Quality Press, 2008