Enrolment No./Seat No_____

GUJARAT TECHNOLOGICAL UNIVERSITY

BE- SEMESTER– VII EXAMINATION – SUMMER 2026

Subject Code:3170313 Date:29-05-2026

Subject Name:Regulatory Standards for Medical Devices

Time:02:30 PM TO 05:00 PM Total Marks:70

Instructions:

1. **Attempt all questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**
4. **Simple and non-programmable scientific calculators are allowed.**

			MARKS
Q.1	**(a)**	What is medical device? Explain types of medical devices including combination devices.	**03**
	(b)	Write in detail market trends for medical devices.	**04**
	(c)	Explain in detail life cycle of medical devices with necessary diagram.	**07**
Q.2	**(a)**	Draw and explain regulatory framework and organization of USFDA.	**03**
	(b)	Explain categorization of medical devices according to ISO 10993.	**04**
	(c)	Explain in detail about development of regulation and standards for medical devices.	**07**
		OR	
	(c)	Explain regulatory controls on medical devices in US.	**07**
Q.3	**(a)**	Explain about Risk Management ISO 14971 for medical devices.	**03**
	(b)	State classification of medical devices in EU.	**04**
	(c)	Explain in detail Quality Systems Regulations (21 CFR Part 820) and Agency Interactions in US.	**07**
		OR	
Q.3	**(a)**	Explain about quality management system ISO 13485 for medical devices.	**03**
	(b)	Explain about Marketing Submissions, Advertising, Labelling and Promotion for medical devices in US.	**04**
	(c)	How to get CE Mark certification? Explain about declaration of conformity.	**07**
Q.4	**(a)**	Describe Regulatory framework or organizations medical device regulation in India.	**03**
	(b)	Explain about Manufacturing-Related Regulation of medical devices in India.	**04**

	(c)	Write a note on Import and export of medical devices in India.	**07**

OR

Q.4	**(a)**	Write a note on Product Registration or Conformity Assessment Route and Time Required for medical devices in india.	**03**
	(b)	Explain about Clinical Trial-Related Regulation of medical devices in India.	**04**
	(c)	Explain in detail about Quality System Regulation for Combined Device–Drug Product in India.	**07**
Q.5	**(a)**	How inspection of Medical Devices conducted in India?	**03**
	(b)	State medical device classification in India.	**04**
	(c)	Explain in detail functions undertaken by DCGI and CDSCO.	**07**

OR

Q.5	**(a)**	What is Role of Related Agencies/Departments in Medical Device Regulations in India?	**03**
	(b)	Explain about Standards of Quality Assurance & Testing for medical device in India.	**04**
	(c)	Describe about Medical Device Regulation Acts & Rules with Upcoming Changes in India.	**07**

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