Seat No.:_____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

BE - SEMESTER–VIII (NEW) EXAMINATION – WINTER 2018

Subject Code: 2180307 **Date: 26/11/2018**

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.**

			MARKS
Q.1	**(a)**	How are devices determined to belong to the higher risk group?	**03**
	(b)	Give definition of medical device according to US FDA and ISO 13485.	**04**
	(c)	Give the categorization of medical devices according to ISO 10993.	**07**
Q.2	**(a)**	What are some of the devices that are provided in combination with drugs?	**03**
	(b)	What are the driving forces behind the development of the medical device?	**04**
	(c)	Explain Life cycle of medical devices from research and development until regulatory approval.	**07**
		OR	
	(c)	Give the classification based on Singapore medical device norms.	**07**
Q.3	**(a)**	How can a medical device improve the quality of life?	**03**
	(b)	Explain functions of DGCI and central government for medical device regulation.	**04**
	(c)	Explain organization of CDSCO.	**07**
		OR	
Q.3	**(a)**	Which Indian organization recently prices of coronary stents? Why?	**03**
	(b)	Whether Registration and import license is required for import of non-notified medical device in India? Justify the answer.	**04**
	(c)	Write a short note on medical device regulatory in India.	**07**
Q.4	**(a)**	Explain the safety aspect of cyber-security during the designing of Medical Devices.	**03**
	(b)	Draw regulatory process chart for Class I EU medical devices.	**04**
	(c)	Explain the main eight principles of Quality Management Systems for Medical Devices (ISO 13485:2003) with the help of diagram.	**07**
		OR	
Q.4	**(a)**	Explain the role of Competent Authority members in EU.	**03**
	(b)	Define the following terms 1. Labeling 2. Post-Marketing	**04**
	(c)	Explain the process of China Compulsory Certification Mark in detail.	**07**
Q.5	**(a)**	Define the following terms with examples. 1) Surface Contacting Devices 2) External Communicating Devices	**03**
	(b)	Enlist the functions undertaken by the FDA and state government for Medical Device regulation in India.	**04**
	(c)	Define CE Marking? Outline the steps to achieve the CE marking for medical device in EU.	**07**
		OR	
Q.5	**(a)**	Is there a single entity that controls all the different regulatory authorities in the different countries? Justify the answer.	**03**
	(b)	Illustrate the difference between Manufacturing-Related Regulation and Clinical Trial-Related Regulation	**04**
	(c)	Describe the regulatory process of Class II & Class III US-FDA Medical devices with the help of flowchart.	**07**