Seat No.: _____ Enrolment No.

GUJARAT TECHNOLOGICAL UNIVERSITY

BE - SEMESTER–VIII(NEW) EXAMINATION – SUMMER 2019

Subject Code:2180307 **Date:15/05/2019**

Subject Name:Regulatory Standards for Medical Devices

Time:10:30 AM TO 01:00 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)**	What are examples of medical devices?	**03**
	(b)	Explain the Safety testing of Medical Devices.	**04**
	(c)	What are some of the devices that are provided in combination with drugs?	**07**
Q.2	**(a)**	Draw the Organization Chart of CDSCO.	**03**
	(b)	Explain the role of below given members in EU. 1) Competent Authority 2) Notified Body.	**04**
	(c)	Explain the main eight principles of Quality Management Systems for Medical Devices (ISO 13485:2003) with the help of diagram.	**07**
		OR	
	(c)	Is there a single entity that controls all the different regulatory authorities in the different countries? Justify the answer.	**07**
Q.3	**(a)**	Explain the categorization of medical device based on ISO 10993.	**03**
	(b)	What are the functions undertaken by DCGI and Central Government for medical Device regulation?	**04**
	(c)	Define CE Marking? Outline the steps to achieve the CE marking for medical device in EU.	**07**
		OR	
Q.3	**(a)**	Explain the safety aspect for cyber-security.	**03**
	(b)	Enlist the functions undertaken by the FDA and state government for Medical Device regulation in India	**04**
	(c)	Explain Life cycle of medical devices from research and development until regulatory approval.	**07**
Q.4	**(a)**	Give Classification of IVD Devices.	**03**
	(b)	Indicate the ISO Standards for below define task. 1) Quality management 2) Risk Management 3) Biological Evaluation 4) Clinical Trials	**04**
	(c)	Discuss the technical material and labeling requirement of medical devices in India.	**07**
		OR	
Q.4	**(a)**	What is the Role of CDRH department in Medical Device Regulation?	**03**
	(b)	Define the following terms with examples. 1) Surface Contacting Devices 2) External Communicating Devices.	**04**
	(c)	Whether Registration and import license is required for import of nonnotified medical device in India? Justify the answer.	**07**

Q.5	**(a)**	Give Definition of Medical Device as per China.	**03**
	(b)	What are the necessary requirements for Premarket Notification 510K Submission for Medical Device?	**04**
	(c)	Describe the regulatory process of Class II & Class III US-FDA Medical devices with the help of flowchart.	**07**

OR

Q.5	**(a)**	Write a note on classification of medical devices in EU.	**03**
	(b)	Write a Short note on : CCC Mark (China Compulsory Certification Mark)	**04**
	(c)	Illustrate the difference between Manufacturing-Related Regulation and Clinical Trial-Related Regulation.	**07**

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