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B.M.S. College of Engineering, Bengaluru-560019

Autonomous Institute Affiliated to VTU

September / October 2023 Supplementary Examinations

Programme: B.E.

Branch: Medical Electronics

Course Code: 19ML6PCMDD

Course: Medical Device Development

Semester: VI

Duration: 3 hrs.

Max Marks: 100

Date: 21.09.2023

Instructions: 1. Answer any FIVE full questions, choosing one full question from each unit.
2. Missing data, if any, may be suitably assumed.

UNIT - I

1	a) Discuss about the status of bio-innovation in India.	06
	b) How are the Bio design processes taking on different roles of providing opportunity and using services across the different business domains?	08
	c) Exemplify the challenges of Computed Tomography (CT) -guided Radio Frequency Ablation (RFA) by Perfint Maxio.	06

OR

2	a) Bring out the salient features of MedTech Innovation.	06
	b) Highlight the design of new medical device steps.	06
	c) Describe the steps in identifying critical unmet need and developing a need specification document.	08

UNIT - II

3	a) Classify medical devices in accordance with the FDA guidelines.	10
	b) Prioritize the safety aspects and precautions to be considered in medical device development.	10

OR

4	a) Explain the following terms with respect to Requirement Analysis: i) Adaptability, ii) Availability, iii) User training, iv) Labelling and v) Disposable.	10
	b) Provide requirements, clauses and standards covered by the ISO guidance document for ISO 13485.	10

UNIT - III

5	a) Describe the use of standards in MedTech devices.	10
	b) Is it necessary corrective and preventive actions (CAPA) in medical device from customer perspectives? Write some Safety and Risk management.	10

Important Note: Completing your answers, compulsorily draw diagonal cross lines on the remaining blank pages. Revealing of identification, appeal to evaluator will be treated as malpractice.

UNIT - IV

6	a) What is HE75 and principles of human factor engineering?	08
	b) Compile the functions of Human Factor Engineering: i) Design Process, ii) Design Verification, iii) Design Validation, iv) Design Review.	08
	c) Draw a functional block diagram of human factor Engineering and mention their components.	04

UNIT - V

7	a) What is the Critical Path Method (CPM)? Elaborate steps involved to find critical path.	10
	b) How to design medical devices with sustainability? Explain.	10
