

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: **10**
i) Adaptability, ii) Availability, iii) User training, iv) Labelling and v) Disposable.
- 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

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|---|----|---|-----------|
| 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

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|---|----|---|-----------|
| 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 |

SUPPLEMENTARY EXAMS 2023