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Sixth Semester B.E. Degree Examination, July/August 2022 Medical Device Regulations and Safety

Time: 3 hrs.

Max. Marks: 100

Note: Answer any FIVE full questions, choosing ONE full question from each module.

Module-1

- 1 a. Explain in detail about medical device safety and Risk management. (10 Marks)
- b. Draw and explain the life span of medical devices. (10 Marks)

OR

- 2 a. Explain the following:
 - i) Quality vs Reliability
 - ii) Reliability vs unreliability. (10 Marks)
- b. Explain different types of reliability. (10 Marks)

Module-2

- 3 a. Write the objective and scope of four GHFT study groups. (10 Marks)
- b. Explain Global Medical Devices Nomenclature (GMDN). (10 Marks)

OR

- 4 a. Explain 510(K) process. (10 Marks)
- b. Explain in detail about GLP's and GMP's. (10 Marks)

Module-3

- 5 a. Explain about European directives and European standardization bodies. (10 Marks)
- b. Explain in detail about European standards development process. (10 Marks)

OR

- 6 a. Define medical devices and explain in detail different types of medical products. (10 Marks)
- b. Explain in detail about identification and choice of notified body. (10 Marks)

Module-4

- 7 a. Explain the standards of the needs of standards as per ISO. (10 Marks)
- b. Explain with flow chart typical process for standard development. (10 Marks)

OR

- 8 a. Write in detail about the national and international standards system. (10 Marks)
- b. Explain the use of standards in device regulation in the recent trends. (10 Marks)

Module-5

- 9 a. Explain International software regulations and standards. (10 Marks)
- b. Write about the move towards one software standards. (10 Marks)

OR

- 10 a. Explain the production and process control by FDA. (10 Marks)
- b. Explain in detail about the design controls by FDA. (10 Marks)