

**PARUL UNIVERSITY**  
**FACULTY OF ENGINEERING & TECHNOLOGY**  
**B.Tech. Winter 2022 - 23 Examination**

**Semester: 7****Subject Code: 203111407****Subject Name: Hospital Information System & Regulatory Standards****Date:08/10/2022****Time: 10:30 am to 01:00 pm****Total Marks: 60****Instructions:**

1. All questions are compulsory.
2. Figures to the right indicate full marks.
3. Make suitable assumptions wherever necessary.
4. Start new question on new page.

**Q.1 Objective Type Questions** - ( Fill in the blanks, one word answer, MCQ-not more than Five in case of MCQ) (All are compulsory) (Each of one mark) **(15)**

1. Define the term: Hospital
2. Define the term: ICU
3. What is Zoning?
4. Define the term Waste
5. Define Nightingale Ward.
6. Enlist the equipments used in Laboratory.
7. Define Inpatient.
8. CDSCO stands for \_\_\_\_\_.
9. Give full form for IVDD.
10. Give the difference between ISO9001 and ISO13485.
11. Mention basic steps to get ISO13485 certification.
12. What is 510(k) and PMA?
13. Why cGMPs are so important?
14. What are the benefits of being qualified for Confirmative Assessment?
15. CENELEC stands for \_\_\_\_\_.

**Q.2** Answer the following questions. (Attempt any three) **(15)**

- A) Explain the classification of medical device based on risk of the device and according to GHTF in European Union.
- B) Give the classification of medical devices as per USA standards.
- C) What are standards? Why do we need standards?
- D) Give classification of OPD. Draw the flow chart of OPD.

**Q.3** A) Define CSSD. Enlist various functions of CSSD and also draw the flow chart for sequence of events done in CSSD. **(07)**

B) Enlist and explain Intramural and Extramural functions of Hospital **(08)**

**OR**

B) Consider Operation Theater (OT) as a point of interest and answer the following questions briefly: **(08)**

- (i) Circulation pattern of OT
- (ii) Factors to be consider for deciding location of OT
- (iii) Criteria for Zoning of OT
- (iv) Safety Hazards for OT

**Q.4** A) What is PDCA model? Explain PDCA model in brief. **(07)**

**OR**

A) What is CE mark? Explain briefly following: **(07)**

- (i) Procedure to obtain CE mark
- (ii) Essential Requirements for obtaining CE mark for medical devices.

B) Explain major phases in the life span of a medical device in brief with necessary block diagram. **(08)**