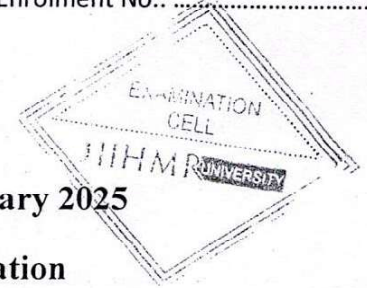


IIHMR UNIVERSITY
MBA Hospital and Health Management
(2023-2025)

Enrolment No.:



Second Year, Term 5 End Term Examination, February 2025

EC-242 Medical Devices in Health Care Organisation

Time - 3 Hours

Maximum Marks: 50 (Minimum Marks 20)

Instructions to students:

- This question paper contains 2 printed pages.
- Don't write anything on the Question Paper except writing your Enrolment No.

Part A

(Maximum Marks: 5)

Q1. Choose the correct option for the following questions (1 mark each):

- a)are defined as medical devices requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by clinical engineers
- a) Refractory Pump
 - b) Refractory Apparatus
 - c) Medical equipment
 - d) None of the above
- b) One of the statement about the marketing features of Urinary catheter is not correct. Identify the incorrect option
- a) Designed for short term bladder catheterization.
 - b) Made from medical grade thermo-sensitive PVC material.
 - c) Irritant to delicate mucous membranes of urethra.
 - d) Perfectly finished closed distal end for smooth & painless insertion.
- c) The license for manufacturing a Class A or B device is issued by the....., while the licensing to manufacture a Class C or D device is issued by the
- a) State Licensing Authority, Central Licensing Authority.
 - b) Central Licensing Authority, State Licensing Authority,
 - c) State Licensing Authority
 - d) Central Licensing Authority
- d) The is the outcome of the bidding process; it is the document that will legally bind the purchaser and supplier to an agreed-upon set of product specifications, delivery requirements, performance and payment obligations of both parties, and legal recourse in the case of non-compliance on either side.
- a) Arbitration
 - b) Embodiment
 - c) License
 - d) Contract
- e) Preferred needle gauge for an intradermal injection ranges from 25g to 30g as the needle width is small **0.5mm to 0.3mm and a length of.....**
- a) 8mm to 13mm
 - b) 80 mm to 130 mm
 - c) 60 mm to 120 mm
 - d) 40 mm to 110 mm

Part B

(Maximum Marks: 15)

Answer the following questions (5 marks each):

- Q2. Define Medical Device as per Section 201(h) of the Food, Drug, and Cosmetic Act. Elaborate the definition taking into account the diagnosis component citing suitable example.
- Q3. You are working as marketing manager of Romsons Medical Devices. Write the marketing communication for N95 PM 0.3 Mask (GS-9038)
- Q4. Elaborate on the Legal and Regulatory framework for medical devices in India.

Part C

(Maximum Marks: 30)

Answer the following questions in detail (10 marks each):

- Q5. Elaborate on the initiatives taken by GOI for promoting medical device sector in India. Cite relevant examples in support of your answer
- Q6. Elaborate the components of Supply Chain Management involved in Medical Devices. Cite relevant examples in support of your answer
- Q7. AIIMS, New Delhi wishes to procure cardiac stents for the Cardiac Surgery department for catering to the needs of the patient undergoing cardiac intervention. You are working as Procurement Manager in AIIMS, New Delhi. Enlist the steps which you will undertake for procuring good quality cardiac stents for AIIMS New Delhi.

