



**MBA Hospital, Health and Development Management
(2022-2024)**

Second Year, Term 6 End Term Examination, March 2024

EC-242 Medical Devices in Health Care Organisation

Time - 3 Hour

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. Fill in the blanks (1 mark each):

- (a). _____ are defined as medical devices requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by clinical engineers.
 - (i) Refractory Pump
 - (ii) Refractory Apparatus
 - (iii) Medical equipment
 - (iv) None of the above
- (b). One of the statement about the marketing features of Urinary catheter is not correct. Identify the **incorrect** option
 - (i) Designed for short term bladder catheterization.
 - (ii) Made from medical grade thermo-sensitive PVC material.
 - (iii) Irritant to delicate mucous membranes of urethra.
 - (iv) 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 _____.
 - (i) State Licensing Authority, Central Licensing Authority.
 - (ii) Central Licensing Authority, State Licensing Authority,
 - (iii) State Licensing Authority
 - (iv) 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.
 - (i) Arbitration
 - (ii) Embodiment
 - (iii) License
 - (iv) Contract
- (e). Preferred needle gauge for a intradermal injection ranges from 25g to 30g as the needle width is small **0.5mm to 0.3mm and a length of _____** .
 - (i) 8mm to 13mm
 - (ii) 80 mm to 130 mm
 - (iii) 60 mm to 120 mm
 - (iv) 40 mm to 110 mm

Part B

(Maximum Marks: 15)

Answer the following questions.

- Q2.** State the significance of Patent Protection of Medical Devices. (5)
- Q3.** You are working as marketing manager of Romsons Medical Devices. Write the marketing communication for N95 PM 0.3 Mask (GS-9038). (5)
- Q4.** Elaborate on the Legal and Regulatory framework for medical devices in India. (5)

Part C

(Maximum Marks: 30)

Answer the following questions in detail.

- Q5.** Elaborate on the classification of medical devices as per the Medical Device Rules, 2017 of GOI. Cite relevant examples in support of your answer. (10)
- Q6.** Elaborate on the steps involved in Marketing of Medical devices in India. Cite relevant examples in support of your answer. (10)
- Q7.** AIIMS, New Delhi wish to procure cardiac stents for the Cardiac Surgery department for catering to the needs of the patient undergoing angioplasty. You are working as Procurement Manger in AIIMS, New Delhi. Enlist the steps which you will undertake for procuring a good quality cardiac stent for AIIMS New Delhi. (10)