Enrolment No.: .....

# IIHMR UNIVERSITY

## School of Pharmaceutical Management

## MBA Pharmaceutical Management

## Batch-15th (2023-2025)

## Second Year, Term 4 End Term Examination, November 2024



## PHRM-744 Promotion of Medical Devices in Hospitals

**Time - 3 Hour** **Maximum Marks: 50 (Minimum Marks: 20)**

**Instructions to students:**

- **This question paper contains 02 printed pages.**
- **Don't write anything on the Question Paper except your Enrolment No.**

### Part A

**(Maximum Marks: 5)**

**Q1. Choose the correct option / Fill in the blank for the following (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).** A _____ for a medical device from the Central Drugs Standards Control Organization (CDSCO) is a document that allows for the export of regulated medical devices in India.

(i) Free Sale Certificate (FSC)
(ii) Free Service Certificate (FSC)
(iii) Free Secure Certificate (FSC)
(iv) None of the above

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## Part B

**(Maximum Marks: 15)**

**Answer the following questions (5 mark 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

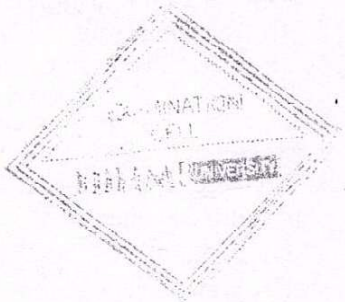
**(Maximum Marks: 30)**

**Answer the following questions in detail (10 mark each).**

**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.

**Q6.** Elaborate the components of Supply Chain Management involved in Medical Devices. Cite relevant examples in support of your answer.

**Q7.** AIIMS, New Delhi wish to procure cardiac Pacemakers for the Cardiac Surgery department for catering to the needs of the patient undergoing cardiac intervention. You are working as Procurement Manger in AIIMS, New Delhi. Enlist the steps which you will undertake for procuring a good quality cardiac pacemaker for AIIMS New Delhi.



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