Roll No. | | | | | | | | | | | | | **Total No. of Pages : 02**

Total No. of Questions : 06

M.Pharmacy (Regulatory Affairs) (Sem.–2)

REGULATORY ASPECTS OF MEDICAL DEVICES

Subject Code : MRA-203T

M.Code : 79818

Date of Examination : 08-07-22

Time : 3 Hrs. **Max. Marks: 75**

INSTRUCTIONS TO CANDIDATES :

1. **Attempt any FIVE questions out of SIX questions.**
2. **Each question carries FIFTEEN marks.**

1. **Define :**

   a. Medical devices

   b. IVDs

   c. ISO

   d. Global Medical Device Nomenclature

   e. UDI

   f. Validation

   g. Diagnostics

   h. Clinical evaluation

2. Classify medical devices? Enumerate principle and life cycle of medical devices.

3. Explain :

   a. Clinical investigation of medical devices as per USA guidelines

   b. Quality system regulation of medical devices in general

4. a. Enumerate regulatory approval process for medical devices as per European Union guidelines.

   b. Highlight in vitro diagnostics as per European Union guidelines.

5. a. What are regulatory registration procedures as per China and Japan guidelines?

   b. Explain the clinical evaluation and investigation as per ASEAN guidelines.

6. Write short note on :

   a. Labelling requirements (as per USA guidelines).

   b. Post marketing surveillance of MD (as per USA guidelines).

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.