

**QP CODE: 213333**

**Reg. No:.....**

**Second Semester M. Pharm Degree Regular/Supplementary Examinations  
November 2025**

**M.Pharm (Regulatory Affairs)**

**Paper - III – Regulatory Aspects of Medical Devices (MRA 203T)**

**(Common for 2019 and 2024 Scheme)**

**Time: 3 Hours**

**Total Marks: 75**

- *Answer all questions to the point neatly and legibly • Do not leave any blank pages between answers • Indicate the question number correctly for the answer in the margin space*
- *Answer all parts of a single question together • Leave sufficient space between answers*
- *Draw table/diagrams/flow charts wherever necessary*

**Essays**

**(3x10=30)**

1. Explain the quality system regulations of medical devices ISO 13485 and quality risk management of medical devices ISO 14971
2. Elaborate on post marketing surveillance of medical devices. Write a note on unique device identification
3. Explain the approval process of in-vitro diagnostics in Europe Union

**Short Notes**

**(9x5=45)**

4. Summary technical document (STED)
5. Global medical device nomenclature (GMDN)
6. Implantable medical device directives
7. Clinical investigation requirements for medical devices in China
8. Explain the regulatory requirements for medical devices in India
9. Mention the good clinical practices for investigation of a medical device according to ISO
10. Adverse event reporting of medical device
11. Product life cycle of medical devices
12. IVD approval process in Japan

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| <b>CORRECTION / NO-CORRECTION FILE</b> |
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**QPCODE: 213333**

**Dated: 12-11-2025**

**Question No.8**

**Replaced with "Compare the approval process of medical devices between USA and European Union."**

**Corrections/Modifications/Replacement of Questions if any shall be made available to all students. Take the print out of the Correction File in such cases and distribute to all students.**

**(Sd/-)**

**CONTROLLER OF EXAMINATIONS**