Reg. No. : | | | | | | | | | | | | |

Question Paper Code: UB204

B.E./B.Tech. DEGREE EXAMINATION, NOV 2025

Professional Elective

21BMV204 - MEDICAL DEVICE REGULATIONS

Biomedical Engineering

(Regulations 2021)

Duration: Three hours Maximum: 100 Marks

Answer ALL Questions

PART A - (10 x 2 = 20 Marks)

1.	Apply post-market surveillance data to revise or update labeling for a medical device. Provide a relevant example of how feedback or incident reports can improve label clarity or safety.	CO2- App
2.	Apply labeling requirements by selecting two essential elements for a Class II medical device and explain how they help ensure regulatory compliance and patient safety.	CO2- App
3.	Discuss how the ISO 14971 to assess the risks of software used in a medical device.	CO1- U
4.	Explain how traceability is maintained in a quality management system.	CO1- U
5.	What is the importance of electrical safety testing for medical devices?	CO1- U
6.	Compare EU MDR vs US FDA in a sentence each for: a) conformity assessment/clearance route, b) post-market surveillance	CO3- App
7.	Expand CDSCO and state its role and What does IMDRF stand for?	CO1- U
8.	Name any two post-market obligations for manufacturers in India	CO1- U
9.	What does in-silico clinical trial mean?	CO1- U
10.	How intelligent design control shortens development cycles.	CO1- U

PART – B (5 x 16= 80 Marks)

11.	(a)	Apply MDR Annex I to identify and justify the inclusion of general safety and performance requirements in the technical file of a reusable surgical instrument (Class I)	CO3 -App	(16)

Or

	(b)	Examine a sample medical device label (provide or describe) and identify any non-compliance issues with regulatory standards.	CO2 -App	(16)
12.	(a)	Apply the principles of ISO 13485:2016 to design a basic QMS structure for a small-scale medical device manufacturing company.	CO3- App	(16)
		Or		
	(b)	Apply risk control measures according to ISO 14971 to mitigate hazards such as electrical shock, software failure, or user error in a medical device.	CO2- App	(16)
13.	(a)	Compare the types of conformity assessment routes followed under the US FDA and EU MDR systems.	CO1- U	(16)
		Or		
	(b)	Summarize the relationship between IEC 60601, ISO 13485, and ISO 14971 standards in ensuring medical device quality, safety, and risk management.	CO1 - U	(16)
14.	(a)	Apply the Indian Medical Device Rules (IMDR) to outline the step-by-step procedure for manufacturing and marketing approval of a new medical device in India.	CO3-App	(16)
		Or		
	(b)	Design a regulatory strategy for an Indian company developing a connected insulin pump .(i) Preclinical studies,(ii) Clinical trial phases,(iii) CDSCO/FDA submission strategy,(iv) Post-market surveillance plan,(v) Digital health compliance .	CO3-App	(16)
15.	(a)	Apply the concept of intelligent design control to minimize development errors and speed up product approval.	CO2-App	(16)
		Or		
	(b)	Apply the FDA and CDSCO guidelines to design a preclinical testing plan for a diagnostic imaging device.	CO2-App	(16)