Reg.No.:												

VIVEKANANDHA COLLEGE OF ENGINEERING FOR WOMEN

[AUTONOMOUS INSTITUTION AFFILIATED TO ANNA UNIVERSITY, CHENNAI]

Elayampalayam – 637 205, Tiruchengode, Namakkal Dt., Tamil Nadu.

Question Paper Code: 120024

B.E. / B.Tech. DEGREE END-SEMESTER EXAMINATIONS – JAN. 2025

Sixth Semester

Biomedical Engineering

U19BMV24 – REGULATORY REQUIREMENTS FOR MEDICAL DEVICES

(Regulation 2019)

Time: Three Hours Maximum: 100 Marks

Answer ALL the questions

Knowledge Levels (KL)	K1 – Remembering	K3 – Applying	K5 - Evaluating
	K2 – Understanding	K4 – Analyzing	K6 - Creating

PART – A

(10 x 2 = 20 Marks)

Q.No.	Questions	Marks	KL	CO
1.	Define Diagnostic Medical device.	2	K1	CO1
2.	Differentiate medical device and an IVD.	2	K2	CO1
3.	State the importance of ISO 13485.	2	K2	CO2
4.	Mention the steps for the certification process of ISO standards.	2	K1	CO2
5.	State the need for conformity assessment.	2	K1	CO3
6.	State the objective of IEC standard.	2	K2	CO3
7.	Define Quality System Regulation.	2	K1	CO4
8.	Give the responsibilities of Central Drug Standard Control Organization.	2	K2	CO4
9.	List the advantages of Regulatory strategy for a medical device manufacturer.	2	K1	CO5
10.	Differentiate post-market surveillance and post market vigilance.	2	K2	CO5

PART – B

(5 x 13 = 65 Marks)

Q.No.		Questions	Marks	KL	CO
11.	a)	Discuss the key provision & objectives of the Medical Device Rules 2017 in ensuring the safety & efficacy of medical devices.	13	K4	CO1

(OR)

	b)	Describe the importance and requirements of medical device labeling.	13	K4	CO1
12.	a)	Explain the requirements for regulatory purposes of ISO 13485:2016.	13	K5	CO2
		(OR)			
	b)	Describe ISO 14971 application of risk management to medical devices.	13	K5	CO2
13.	a)	Explain in detail about the IEC Conformity Assessment Procedures according to Medical Device Regulations.	13	K4	CO3
		(OR)			
	b)	Describe in detail about medical device regulatory system in the USA.	13	K4	CO3
14.	a)	Analyses the measures taken by the central government towards streamline the approval process for medical devices.	13	K3	CO4
		(OR)			
	b)	Compare & contrast the approaches adopted by different state in India towards regulating medical devices.	13	K3	CO4
15.	a)	Explain the key considerations for formulating an effective Regulatory Strategy.	13	K3	CO5
		(OR)			
	b)	Discuss the phases of clinical trials. Evaluate the significance of each phase.	13	K3	CO5

PART – C

(1 x 15 = 15Marks)

Q.No.		Questions	Marks	KL	CO
16.	a)	List out the medical devices under class I and class II category. Explain the process involved in bringing these devices to market.	15	K6	CO1
		(OR)			
	b)	Discuss the steps and processes involved in the certification of medical devices.	15	K5	CO2