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: 12006

B.E. / B.Tech. DEGREE END-SEMESTER EXAMINATIONS – MAY / JUNE 2024
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.	What are In Vitro Diagnostics? Why are they important?	2	K2	CO1
2.	Differentiate between medical devices, IVDs and combinational products from pharmaceuticals by giving examples.	2	K2	CO1
3.	State the salient features of ISO 13485 guidelines.	2	K1	CO2
4.	What are QMS and QA in medical device regulation?	2	K1	CO2
5.	State the role of IEC regulatory system in ensuring product safety.	2	K2	CO3
6.	How does the IEC contribute to global trade?	2	K2	CO3
7.	Draw the Organization Chart of CDSCO.	2	K2	CO4
8.	Enlist the Medical Device Regulation Acts in India with related amendments.	2	K1	CO4
9.	Define "Clinical Trial".	2	K1	CO5
10.	Identify the significance of digital technology in clinical trials.	2	K2	CO5

PART – B

(5 x 13 = 65 Marks)

Q.No.		Questions	Marks	KL	CO
11.	a)	Define medical device and give the classification of medical device according to medical device rules 2017 India. Explain each classification.	13	K2	CO1

		(OR)			
	b)	Discuss about labeling of medical devices and its requirement.	13	K2	CO1
12.	a)	What is the ISO standard for the applications of risk management to medical devices? Describe different types of risks addressed by it.	13	K2	CO2
		(OR)			
	b)	Explain the main Eight Principles of Quality Management Systems for Medical Devices (ISO 13485) with the help of a diagram to illustrate them.	13	K1	CO2
13.	a)	Explain the IEC international standards and conformity assessment for medical devices.	13	K2	CO3
		(OR)			
	b)	Compare and contrast the regulatory framework for medical devices in the USA and the EU.	13	K2	CO3
14.	a)	Explain the importance of product registration in ensuring the safety & efficacy of medical devices.	13	K2	CO4
		(OR)			
	b)	Write a note on the functions undertaken by DGGI and Central Government in enforcing medical device regulations.	13	K2	CO4
15.	a)	Describe the regulatory process of Class II & Class III US-FDA Medical devices with the help of flowchart.	13	K2	CO5
		(OR)			
	b)	Discuss about digital health regulations in detail.	13	K2	CO5

PART – C

(1 x 15 = 15 Marks)

Q.No.		Questions	Marks	KL	CO
16.	a)	Discuss the major highlights for the medical devices and in vitro diagnostics as per European Union? Also discuss the implications of medical device rules on medical devices.	15	K2	CO3
		(OR)			
	b)	Describe the key considerations in designing preclinical trials for medical devices, including study objectives selection of animal models, and regulatory requirements.	15	K2	CO2