B. Tech. Sem – VIII (Biomedical Engg.) (2014 COURSE) (CBCS) :
SUMMER - 2019
SUBJECT: MEDICAL DEVICES STANDARDS

Day: Thursday
Date: 23/05/2019

Time: 02.30 PM TO 05.30 PM
Max Marks : 60

S-2019-2933

N.B. :

1) All questions are **COMPULSORY**.
2) Figures to the right indicate **FULL** marks.
3) Assume suitable data, if necessary.

Q. 1 What the standardization is preferred for medical devices? Give one example of any medical device which is standardized and explain. **(10)**

OR

Q. 1 Discuss the role of standards in the assessment of medical devices. **(10)**

Q.2 **a)** State and explain three major international standardization organizations. **(05)**

b) How the standards are identified? Give any two examples with appropriate explanation. **(05)**

OR

Q.2 List and explain the advantages of using voluntary standards. **(10)**

Q.3 Enlist the major phases in life span of a medical device and elaborate each phase. **(10)**

OR

Q.3 List various stakeholders who share responsibilities for medical device safety and performance. **(10)**

Q.4 What are the critical elements for regulatory attention? Explain all with respect to safety and performance. **(10)**

OR

Q.4 Explain a common framework for medical device regulations. **(10)**

Q.5 **a)** What are the final guidelines from GHTF? **(05)**

b) Write a note on 'GMDN'. **(05)**

OR

Q.5 Explain the current focus of work of the GHTF study groups. Also classify GHTF groups. **(10)**

Q.6 How does one can increase the knowledge of medical device sector? **(10)**

OR

Q.6 Explain with the help of pi-chart: **(10)**

i) Global statistics on medical device production
ii) Advantages of a national policy

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