B. TECH. (CBCS - 2014 COURSE) SEM – VIII (BIOMEDICAL ENGG.) : SUMMER - 2018

SUBJECT: MEDICAL DEVICES STANDARDS

Day: **Saturday** Time: **02.30 PM TO 05.30 PM**
Date: **02/06/2018** **S-2018-4713** Max Marks : 60

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

Q. 1 What are standards? List and explain specification in standards? **(10)**

OR

Q. 1 Why do we need standards? What are the various purposes behind making medical devices standardize? Explain it in detail. **(10)**

Q.2 Give reason "International standards are a building block for harmonized regulatory processes". **(10)**

OR

Q.2 Write short notes on: **(10)**
i) National Standard System
ii) Process for standards development

Q.3 **a)** How do you give optimum assurance of medical device safety? **(05)**
b) Discuss the terms clinical effectiveness and performance with respect to medical devices. **(05)**

OR

Q.3 Define following terms with example: **(10)**
i) Risk Assessment
ii) Risk Analysis
iii) Risk Evaluation

Q.4 Discuss the following stages with respect to government regulations. **(10)**
i) Pre-market
ii) Placing on-market

OR

Q.4 Write a notes on : **(10)**
i) Life Span of Medical Device
ii) Medical Device Safety

Q.5 Define the term Global Harmonization Task force (GHTF). What is the purpose of GHTF? Explain in detail. **(10)**

OR

Q.5 Discuss the importance of Global Medical Device Nomenclature (GMDN). How GMDN is to be used by regulators for classification and registration of medical devices? **(10)**

Q.6 Write a notes on : **(10)**
i) Product representation control
ii) Promoting compliance and cooperation

OR

Q.6 What is the optimizing use of regulatory resources? List and explain various activities to establish a comprehensive guideline on medical device management. **(10)**

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