Reg.No. \_\_\_\_\_\_\_\_\_\_\_\_

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**End Semester Examination – Nov/Dec – 2018**

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| **Code :** | **15EI2029** | **Duration :** | **3hrs** |
| **Sub. Name :** | **PATIENT AND DEVICE SAFETY** | **Max. marks :** | **100** |

**ANSWER ALL QUESTIONS (5 x 20 = 100 Marks)**

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| **Q. No.** | **Sub Div.** | **Questions** | **Course**  **Outcome** | **Marks** |
| 1. | a. | Analyse the various requirements for binding protection goals to improve device safety. | CO2 | 15 |
| b. | Relate Quality and Reliability. | CO1 | 5 |
| (OR) | | | | |
| 2. | a. | Describe the important features of various types of reliability. | CO1 | 12 |
| b. | Summarize the risk balance factors for elevating and reducing perceived risk. | CO3 | 8 |
|  |  |  |  |  |
| 3. | a. | Identify the need for failure assessment and documentation. | CO2 | 10 |
| b. | Explain the features of risk management process. | CO2 | 10 |
| (OR) | | | | |
| 4. | a. | Identify the different measures for avoiding risk of accidents with an example. | CO2 | 15 |
| b. | Comment briefly on safety analysis tools. | CO2 | 5 |
|  |  |  |  |  |
| 5. | a. | Summarize the various factors related with an environment safety. | CO3 | 12 |
| b. | Explain in detail about the various stages of device life cycle. | CO1 | 8 |
| (OR) | | | | |
| 6. | a. | Illustrate the various categories for safety requirements. | CO1 | 8 |
| b. | Comment briefly on the effects of electric safety sources with an example. | CO1 | 12 |
|  |  |  |  |  |
| 7. |  | Explain in detail about different EMI noise coupling mechanisms and provide the steps to control the noises. | CO2 | 20 |
| (OR) | | | | |
| 8. | a. | Mention the specific beneficial outcomes of applying human factors/usability engineering to medical devices. | CO3 | 10 |
| b. | Explain in detail about the role of Investigational Device Exemptions. | CO3 | 10 |
|  | |  |  |  |
|  | | **Compulsory**: |  |  |
| 9. |  | Discuss the followings:  a. Institutional Review Board b. Medical Device Directive | CO3 | 20 |