TEVETA

Technical Education, Vocational and Entrepreneurship Training Authority

DIPLOMA IN BIOMEDICAL ENGINEERING

LEVEL 6 YEAR III EXAMINATIONS

FINAL INTEGRATED SUMMATIVE EXAMINATIONS

SITTING: NOVEMBER / DECEMBER 2025

SUBJECT: REGULATIONS, STANDARDS AND ETHICS

TIME: THREE (3) HOURS **TOTAL MARKS: 100**

PASS MARK: 50

INSTRUCTIONS TO CANDIDATE

1. Write your Examination number and National Registration Card (NRC) number on the answer booklet provided. Ensure you append your signature in the space provided on the answer booklet.
2. Write the ANSWER SCRIPT SERIAL NUMBER on the examination register and on the entry slip.
3. There are EIGHT (8) questions in this paper. Question one (1) is compulsory, answer FOUR (4) questions from the remaining SEVEN (7) questions.
4. Diagrams may be used where necessary to clarify your answer.
5. Cell phone and programmable calculators are not allowed in the examination room

DO NOT TURN THIS PAGE UNTIL YOU ARE TOLD TO DO SO

QUESTION 1 (COMPULSORY)

a) Explain the declaration of Helsinki by highlighting the main issues. [10 marks]

b) Describe **five (5)** benefits of the declaration of Helsinki to society. [10 marks]

[TOTAL MARKS 20]

QUESTION 2

Describe **ten (10)** regulations that should be followed when dealing with medical equipment. [20 marks]

[TOTAL MARKS 20]

QUESTION 3

a) State the meaning of the following acronyms:
   i) GHTF [2 marks]
   ii) GMP [2 marks]
   iii) GMDN [2 marks]
   iv) FDA [2 marks]

b) Explain **three (3)** functions of GHTF [6 marks]

c) Describe **three (3)** areas that can help minimize risks relating to medical equipment in healthcare delivery. [6 marks]

[TOTAL MARKS 20]

QUESTION 4

a) State the acronym FDA in full [2 marks]

b) General controls are the minimum regulations that apply to all FDA regulated medical devices. Explain **five (5)** elements included in general controls according to the FDA. [10 marks]

c) Describe **four (4)** risk classification determinants according to FDA. [8 marks]

[TOTAL MARKS 20]

QUESTION 5

a) In relation to European Union standards, define a "Notified body" [2 marks]

b) State the body that issues a Declaration of Conformity [2 marks]

c) Describe **six (6)** elements included in a Declaration of Conformity [12 marks]

d) Explain the purpose of the Competent Authority (CA). [4 marks]

[TOTAL MARKS 20]

QUESTION 6

a) Define user error [2 marks]

b) Explain **five (5)** ways in which user errors can be minimized in a hospital [10 marks]

c) Differentiate a hazard from a risk [4 marks]

d) Describe **two (2)** steps involved in risk assessment [4 marks]

[TOTAL MARKS 20]

QUESTION 7

a) Define an "adverse event" [2 marks]

b) Explain **five (5)** causes of "adverse events" in health facilities. [10 marks]

c) Describe **four (4)** pieces of data that is collected during post market surveillance [8 marks]

[TOTAL MARKS 20]

QUESTION 8

a) Define a standard [2 marks]

b) Explain **eight (8)** requirements for developing a standard. [18 marks]

s[TOTAL MARKS 20]