TEVETA

Technical Education, Vocational and Entrepreneurship Training Authority

DIPLOMA IN BIOMEDICAL ENGINEERING

LEVEL 6 YEAR III EXAMINATIONS

FINAL INTEGRATED SUMMATIVE EXAMINATIONS

SITTING: JULY / AUGUST 2026

SUBJECT: REGULATIONS, STANDARDS AND ETHICS

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

INSTRUCTIONS TO CANDIDATE **PASS MARK: 50**

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. This paper has TWO (2) Sections.
   - Answer ALL questions in section A.
   - Answer FIVE (5) questions in Section B. Question one (1) is compulsory then answer any four (4) questions from the remaining six (6) questions.
4. Diagrams may be used where necessary to clarify your answer.
5. Cell phones and programmable calculators are not allowed in the examination room

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

SECTION A: MULTIPLE CHOICE QUESTIONS **TOTAL MARKS: 20**
ANSWER ALL QUESTIONS BY CHOOSING THE BEST OPTION

1. What is the primary goal of medical equipment safety? To...
   A. reduce hospital costs
   B. prevent hazards during equipment, use
   C. increase patient throughput
   D. improve staff comfort

2. How does medical equipment performance relate to safety?
   A. Performance and safety are unrelated
   B. Good performance enhances safety by reducing risks
   C. Safety reduces performance efficiency
   D. Performance only affects financial cost

3. Which participant is mainly responsible for designing and certifying medical equipment?
   A. Vendors
   B. Users (clinicians)
   C. Manufacturers
   D. Regulators

4. Who enforces compliance with national standards and conducts inspections?
   A. Maintenance staff
   B. Government and regulatory agencies
   C. Vendors
   D. Nurses and clinicians

5. Which of the following is a shared responsibility among all stakeholders?
   A. Profit maximization
   B. Patient safety culture
   C. Equipment disposal
   D. Hospital budgeting

6. Which agency regulates medical devices in the United States?
   A. EMA
   B. FDA
   C. ISO
   D. WHO

7. Which stage of regulatory control involves monitoring adverse events and recalls?
   A. Pre-market approval
   B. Market authorization
   C. Post-market surveillance
   D. Continuous improvement

8. What is the purpose of a Declaration of Conformity? To...
   A. certify compliance with applicable regulations
   B. reduce hospital costs
   C. train hospital staff
   D. replace ISO standards

9. Which of the following is a regulatory tool ensuring traceability and safe use?
   A. Labeling requirements
   B. Hospital budgeting
   C. Patient satisfaction surveys
   D. Peer reviews

10. What was the main purpose of the Global Harmonisation Task Force (GHTF)? To...
   A. increase hospital profits
   B. harmonize medical device regulations internationally
   C. replace ISO standards
   D. train hospital staff

11. Which organization succeeded the GHTF?
   A. FDA
   B. WHO
   C. IMDRF
   D. EMA

12. Which nomenclature system is most widely used internationally for coding medical devices?
   A. UMDNS
   B. GMDN
   C. EMDN
   D. ISO 9001

13. The UMDNS system was developed by:
   A. WHO
   B. ECRI Institute
   C. FDA
   D. ISO

14. Which nomenclature system is specifically adopted under EU Medical Device Regulation (MDR)?
   A. GMDN
   B. UMDNS
   C. EMDN
   D. ISO 13485

15. Why are nomenclature systems important in hospitals? They
   A. reduce patient waiting times
   B. standardize device classification for inventory, procurement, and regulation
   C. increase hospital revenue
   D. replace clinical staff training

16. What was a major focus of the 2024 revision of the Declaration of Helsinki?
    A. Reducing hospital costs
    B. Ethical use of AI in medical research
    C. Increasing patient waiting times
    D. Eliminating clinical trials

17. Which ethical concern is most relevant to clinical trials in developing countries?
    A. Profit maximization
    B. Exploitation of vulnerable populations
    C. Reducing equipment costs
    D. Increasing hospital staff salaries

18. Why have recent changes in medical research ethics come about? To ...
    A. harmonize global standards and address new technologies
    B. reduce the number of hospitals
    C. eliminate informed consent
    D. increase competition among regulators

19. Which emerging technology raises concerns about bias and transparency?
    A. Telemedicine
    B. Artificial Intelligence (AI)
    C. Dialysis Machines
    D. Infusion pumps

20. Which ethical dimension ensures participants in developing countries benefit from clinical trials?
    A. Equitable access to outcomes
    B. Increased hospital profits
    C. Reduced staff workload
    D. Faster equipment disposal

SECTION B TOTAL MARKS 80

THERE ARE SEVEN (7) QUESTIONS IN THIS SECTION, ANSWER FIVE (5) QUESTIONS. QUESTION ONE (1) IS COMPULSORY.

QUESTION 1 (COMPULSORY)

a) Explain **five (5)** importance of having safety standards in hospital settings. [10 marks]

b) Describe how risk management processes (identification, assessment, control, monitoring) reduce hazards. [10 marks]

[TOTAL MARKS 20]

QUESTION 2

a) State the main purpose of labeling according to EU regulations. [2 marks]

b) Indicate **three (3)** elements of a declaration of conformity. [3 marks]

c) Explain **five (5)** ways used by a competent authority (CA) to monitor products placed on the market. [10 marks]

[TOTAL MARKS 15]

QUESTION 3

a) Explain the purposes for the Global Harmonization Task Force (GHTF) [5 marks]

b) Describe **five (5)** Common Medical Device Regulations across the world. [10 marks]

[TOTAL MARKS 15]

QUESTION 4

a) Define risk-benefit ratio [3 marks]

b) Describe **four (4)** pieces of information included in a patient information sheet used when obtaining informed consent. [12 marks]

[TOTAL MARKS 15]

QUESTION 5

a) Explain the following;

i) Objective risk assessment [3 marks]

ii) Subjective risk perception [3 marks]

b) Describe **three (3)** factors that influence how workers perceive risks in the workplace. [9 marks]

[TOTAL MARKS 15]

QUESTION 6

a) Describe **five (5)** major phases in the life cycle of medical equipment. [15 marks]

[TOTAL MARKS 15]

QUESTION 7

a) Define clinical effectiveness in relation to medical devices. [2 marks]

b) List **four (4)** examples of medical devices where technical features (such as alarms, displays, or sensors) are critical for safe operation. [4 marks]

c) Explain **three (3)** reasons why alarm system in a medical device is considered essential even though it does not directly treat the patient. [9 marks]

[TOTAL MARKS 15]