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TECHNICAL UNIVERSITY OF KOŠICE

UNIVERSIDAD DE GRANADA

University of Hradec Králové

M10 – Product Design

TEST

Question 1: In case of medical devices, which regulation must be followed in the European Union?

Please, choose one option:

1. FDA
2. MDD
3. MDR

Question 2: What is “indented use”?

Please, choose one option:

1. Defining under what circumstances or under what conditions this particular product could be used.
2. The label says exactly what the product is used for.
3. Both answers are correct.

Question 3: What for stands an UDI?

Please, choose one option:

1. Uniform Device Identification
2. Ultimate Device Identification
3. Unique Device Identification

Question 4: Why we need the MD classification?

Please, choose one option:

1. In order to apply to medical devices an appropriate conformity assessment procedure.
2. In order to set up a system of classification rules within the Directive, so that each manufacturer could classify its own devices.
3. Both answers are correct.

Question 5: Label of the product must:

Please, choose one option

1. adjust the language to the relevant audience.
2. not be visible for audience
3. contain instructions for use visible on the outside label.

Question 6: Which ISO norm describes only risk management of medical devices?

Please, choose one option

1. ISO 14971
2. ISO 13485
3. ISO 9001

Question 7: Define Verification:

Please, choose one option

1. Confirmation by examination and provisions of objective evidence that the particular requirements for a specific intended use are fulfilled
2. Confirmation by examination and provisions of objective evidence that specified requirements have been fulfilled
3. Confirmation by examination and provisions of objective evidence that non-specified requirements have been fulfilled

Question 8: Define Validation:

Please, choose one option

1. Confirmation by examination and provisions of objective evidence that the particular requirements for a non-specific intended use are fulfilled
2. Confirmation by examination and provisions of objective evidence that the particular requirements for a specific intended use are fulfilled
3. Confirmation by examination and provisions of objective evidence that specified requirements have been fulfilled

Question 9: The medical device shelf life is not determined by:

Please, choose one option

1. Storage conditions
2. Transportation
3. Users education

Question 10: Quality Management System Documentation is described in:

Please, choose one option

1. IEC 60601
2. ISO 14000
3. ISO 9001

Testing Set - Evaluation/Grading Criteria

Clearly state how the module of course's requirements are evaluated.

<text>

Túto časť skopírovať do Syllabus Structure, bod 12.

Correct Answers

Question 1 : In case of medical devices, which regulation must be followed in the European Union?

1. FDA

Question 2: What is "indended use"?

2. The label says exactly what the product is used for.

Question 3: What for stands an UDI?

3. Unique Device Identification

Question 4: Why we need the MD classification?

3. Both answers are correct.

Question 5: Label of the product must:

1. adjust the language to the relevant audience.

Question 6: Which ISO norm describes only the risk management of medical devices?

1. ISO 14971

Question 7: Define Verification:

2. Confirmation by examination and provisions of objective evidence that specified requirements have been fulfilled

Question 8: Define Validation:

2. Confirmation by examination and provisions of objective evidence that the particular requirements for a specific intended use are fulfilled

Question 9: The product shelf life is not determined by:

3. Users education

Question 10: Quality Management System Documentation is described in:

3. ISO 9001