X

Unit 3 - Week 1

Register for Certification exam

Course outline

How to access the portal

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Week 1

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Assignment 1

The due date for submitting this assignment has passed.
As per our records you have not submitted this assignment. **Due on 2019-03-13, 23:59 IST.**

IVDs are substances that are intended for the use in _____ (i), of _____ (ii) in human being or animals

1) _____ (i) ?

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) diagnosis

1 point

2) _____ (ii) ?

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) disease/disorders
(Type: String) disease
(Type: String) disorders

1 point

Scope of notified bodies only include class _____ (i) , and class _____ (ii) in medical devices.

3) _____ (I) ?

No, the answer is incorrect.

Government of India
Ministry of Human Resource De

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) B

0.5 points

5) Import of all classes of medical devices are controlled by ***1 point***

- State Licensing Authorities
- Central Licensing Authority

No, the answer is incorrect.
Score: 0

Accepted Answers:
Central Licensing Authority

6) Match the following ***4 points***

A. Low risk	1. Class A
B. High risk	2. Class B
C. Moderate high risk	3. Class C
D. Low moderate risk	4. Class D

- 4,2,1,3
- 1,4,3,2
- 2,1,4,3
- 3,2,4,1

No, the answer is incorrect.
Score: 0

Accepted Answers:
1,4,3,2

7) Medical Devices Rules 2017 has _____ Rules

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: Numeric) 96

1 point

8) Medical Devices Rules 2017 has _____ Chapters

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: Numeric) 12

1 point

9) Medical Devices Rules 2017 has _____ Schedules

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: Numeric) 08
(Type: Numeric) 8

1 point

10) Medical Devices Rules 2017 has _____ Forms

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: Numeric) 40

1 point

11) G.S.R. _____ dated the 31 January 2017 to have specific requirements for import, manufacture, sale and distribution of medical devices and in vitro diagnostics in the country.

Hint

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) 78 (E)

1 point

12) What GMP is to a drug _____ is to a device.

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) QMS

1 point

13) All notified bodies for medical devices should be registered with _____.

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) CDSCO

1 point

Medical device is any instrument, apparatus, appliance, software, material, or other article whether used alone or in combination, including the software to be used for _____ (i) and/or _____ (ii) purposes in human.

14) _____ (i) ?

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) diagnostic
(Type: String) Diagnostic

1 point

15)_____ (ii) ?

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) therapeutic
(Type: String) Therapeutic

1 point

16)Manufacture of class A and B are controlled by _____ while class C and D are controlled by _____ ***1 point***

- State Licensing Authorities and Central Licensing Authority
- Central Licensing Authority and State Licensing Authorities
- Central Licensing Authority in both cases
- None of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
State Licensing Authorities and Central Licensing Authority

17)Basic principle of classification of medical device is _____ based.

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) risk

1 point

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