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

2) _______ (ii) ?

No, the answer is incorrect.
Score: 0
Accepted Answers:
(Type: String) disease/disorders
(Type: String) disease
(Type: String) disorders

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

3) _______ (i) ?

No, the answer is incorrect.
No, the answer is incorrect.
Score: 0
Accepted Answers:
(Type: String) B

5) Import of all classes of medical devices are controlled by

- State Licensing Authorities
- Central Licensing Authority

No, the answer is incorrect.
Score: 0
Accepted Answers: Central Licensing Authority

6) Match the following

| 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

8) Medical Devices Rules 2017 has ______ Chapters

No, the answer is incorrect.
Score: 0
Accepted Answers: (Type: Numeric) 12

9) Medical Devices Rules 2017 has ______ Schedules
No, the answer is incorrect.
Score: 0
Accepted Answers:
(Type: Numeric) 08
(Type: Numeric) 8

1 point

Medical Devices Rules 2017 has _______ Forms

No, the answer is incorrect.
Score: 0
Accepted Answers:
(Type: Numeric) 40

1 point

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.

1 point

What GMP is to a drug _________ is to a device.

No, the answer is incorrect.
Score: 0
Accepted Answers:
(Type: String) QMS

1 point

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.

1 point

___________ (i) ?
15) _________ (i) ?

No, the answer is incorrect.
Score: 0
Accepted Answers:
(Type: String) diagnostic
(Type: String) Diagnostic

16) Manufacture of class A and B are controlled by __________ while class C and D are controlled by _______________

- 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