SUPPLEMENTARY
MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)
M.Pharm. Sem-II REGULATORY AFFAIRS :SUMMER- 2022
SUBJECT : REGULATORY ASPECTS OF MEDICAL DEVICES

Day : Monday | Time : 10:00 AM-01:00 PM

Date : 19-09-2022 | **S-20790-2022** | Max. Marks : 75

N.B.

1) **Q.No.1** and **Q.No.5** are **COMPULSORY**. Out of the remaining questions attempt **ANY TWO** questions from each section.
2) Answer to both the section should be written in **SEPARATE** answer books.
3) Figures to the **RIGHT** indicate **FULL** marks.

SECTION – I

Q.1 Discuss Risk based classification system in detail. **[08]**

Q.2 Discuss Quality Risk Management of medical devices in detail. **[15]**

Q.3 Discuss Good Clinical Practices for Medical Devices. **[15]**

Q.4 Write notes on **ANY TWO** of the following: **[15]**

a) ISO 14971

b) Adverse Event Reporting

c) Global Medical Device Nomenclature

SECTION – II

Q.5 Discuss Unique Device Identification (UDI). **[07]**

Q.6 Discuss medical device approval process in EU in detail. **[15]**

Q.7 What are In vitro Diagnostics (IVD)? How are they evaluated for stability? **[15]**

Q.8 Write notes on **ANY TWO** of the following: **[15]**

a) Medical device approval in Japan

b) 510K

c) Risk based classification

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