#### IVD/Misc/196/2020 Central Drugs Standard Control Organisation Directorate General of Health Services Ministry of Health & Family Welfare (Diagnostic Division)

FDA Bhawan, Kotla Road New Delhi-110002

E13 SEP 2020

Dated:

#### Notice

#### Subject: Classification of non-notified Medical Devices-reg.

As per S.O 648(E) & G.S.R 102(E) published on date 11.02.2020 the medical devices which are covered under the definition, will be regulated in phase-wise manner. In accordance to MDR-2017 Chapter II, Rule 4 (3) the Central Licensing Authority needs to classify such medical devices as per risk based approach. In order facilitate the process to classify all such In-Vitro Diagnostic medical devices, the devices are divided into 03 categories and examined as per the classification followed internationally and First Schedule of MDR-2017. (The draft of classification of such medical devices is annexed for finalization.)

All concerned associations/stakeholders are requested to forward their comments at e-mail ID <u>cdsco.class.md@gmail.com</u> within 30 days from date of issue.

(Dr. V.G. Somani) Drugs Controller General (I)

To, All stakeholders/associations through CDSCO website.

### List of Categories of Non- Notified In-Vitro Diagnostic Medical Device

| Sr. No. | Category       |
|---------|----------------|
| 1       | IVD Analyzer   |
| 2       | IVD Instrument |
| 3       | IVD Software   |

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## CATEGORY: IVD ANALYZER

## TOTAL NO. OF IVD ANALYZER:

53 Nos.

|            | List of In-Vitro Diagnostic Medical Devices (IVD Analyzers)<br>under provisions of sub-rule (2) rule 4 of the Medical Devices Rules, 2017 |   |   |   |  |  |  |
|------------|---|---|---|---|--|--|--|
| Sr.<br>No. | Category  | Name of the<br>In-Vitro<br>Diagnostic<br>Medical Devices<br>(IVD Analyzers) |   | Intended use  |  |  |  |
| 1          | Clinical<br>chemistry   | Alcohol body-<br>fluid analyser   | В | An instrument intended to determine the concentration of alcohol in a body-fluid specimen.  |  |  |  |
| 2          |   | Amino acid<br>analyser  | В | An instrument intended to be used for the<br>qualitative and/or quantitative in vitro<br>determination of individual amino acids in a<br>protein sample obtained from a clinical<br>specimen. |  |  |  |
| 3          |   | Bilirubinometry<br>analyser   | В | A device that measures directly or indirectly the bilirubin concentration in blood or other samples.  |  |  |  |
| 4          |   | Catecholamines<br>analyser  | В | A device that measures catecholamine concentration in biological samples.   |  |  |  |
| 5          |   | Chemiluminesce<br>nt immunoassay<br>analyser                                | С | An instrument intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen.                                |  |  |  |
| 6          |   | Chloride<br>coulometric<br>titration analyser                               | В | An instrument intended to be used for the quantitative measurement of chloride in a clinical specimen using a coulometric titration.  |  |  |  |
| 7          |   | Cholesterol<br>analyser   | В | A device that measures the cholesterol in serum/whole blood.  |  |  |  |
| 8          |   | Clinical<br>chemistry<br>analyser   | С | An instrument intended to be used for the qualitative and/or quantitative determination of one or multiple clinical chemistry analytes in a clinical specimen.                                |  |  |  |
| 9          |   | Creatinine<br>analyser  | В | A device that measures creatinine concentration in urine or serum sample.   |  |  |  |

| Sr.<br>No. | Category | Name of the<br>In-Vitro<br>Diagnostic<br>Medical Devices<br>(IVD Analyzers) |   | Intended use   |
|------------|----------|---|---|--|
| 10         |          | Enzyme analyser   | В | A device that measures the enzymatic activity of the sample for diagnosis.   |
| 11         |          | Glycated<br>haemoglobin<br>(HbA1C)<br>analyser                              | В | An instrument intended to be used for the<br>quantitative measurement of glycated<br>haemoglobin (HbA1c) in a clinical<br>specimen.  |
| 12         |          | High<br>performance<br>liquid<br>chromatography<br>analyser                 | С | An instrument designed to use high<br>performance liquid chromatography (HPLC)<br>for the qualitative and/or quantitative in vitro<br>determination of chemical and/or biological<br>markers in a clinical specimen. |
| 13         |          | Identification and<br>Antibiotic<br>susceptibility<br>analyser              | В | A device that identifies<br>infectious/pathogenic microorganisms by<br>photometry such as absorption,<br>fluorescence and luminescence, and<br>measures the susceptibility to therapeutic<br>drugs.                  |
| 14         |          | Ion-selective<br>analyser   | В | An instrument intended to be used for the quantitative measurement of electrolytes and/or other ions in a clinical specimen.   |
| 15         |          | Lactate analyser  | В | An instrument used to the determine the concentration of lactate in various body fluids using the lactate oxidase fixation electrode.  |
| 16         |          | Lipid profile<br>analyser   | В | An instrument intended to be used for the qualitative and/or quantitative in vitro determination of lipid profile analytes in a clinical specimen.   |
| 17         |          | Nitrogen body-<br>fluid-sample<br>analyser                                  | В | An instrument used to analyse the nitrogen (N2) content in a bodily fluid.   |
| 18         |          | Protein analyser  | В | A device used to measure concentration<br>and to identify specific proteins present in a<br>clinical specimen.   |

| Sr.<br>No. | Category   | Name of the<br>In-Vitro<br>Diagnostic<br>Medical Devices<br>(IVD Analyzers) | MDR 2017 |  |
|------------|------------|---|----------|--|
| 19         |            | Radioimmunoass<br>ay analyser   | В        | An instrument intended to be used for the<br>qualitative and/or quantitative in vitro<br>determination of chemical and/or biological<br>markers in a clinical specimen using an<br>immunological method which utilizes a<br>radiometric detection system to detect the<br>presence of immune complexes labelled<br>using a radioisotope. |
| 20         |            | Urine analyser  | В        | An instrument intended to be used for the<br>qualitative and/or quantitative in vitro<br>determination of various chemical and<br>cellular constituents of a clinical urine<br>specimen.   |
| 21         | Hematology | ABO/Rh(D)<br>blood grouping<br>analyser                                     | D        | An instrument intended to be used to<br>perform blood group testing to determine<br>the ABO and Rh(D) status of clinical<br>specimens.   |
| 22         |            | Blood cell count<br>analyser  | В        | A device that quantifies the formed<br>elements in the blood (i. e. , erythrocytes,<br>leukocytes, and platelets) by<br>electroimpedance, optical scattering or dye<br>binding.  |
| 23         |            | Blood<br>coagulation<br>analyser  | С        | An instrument intended to be used for the qualitative and/or quantitative in vitro determination of one or multiple coagulation components involved in haemostasis in a clinical specimen.   |
| 24         |            | Blood<br>group/antibody<br>screening<br>analyser                            | С        | An instrument intended to be used to<br>perform pre-transfusion blood group testing,<br>red cell antibody screening/identification<br>and/or red cell phenotyping of clinical<br>specimens or donor specimens in order to<br>determine suitability for transfusion or<br>transplantation.  |

| Sr.<br>No. | Category | Name of the<br>In-Vitro<br>Diagnostic<br>Medical Devices<br>(IVD Analyzers) |   | Intended use   |
|------------|----------|---|---|--|
| 25         |          | Co-oximetry<br>analyser   | С | An instrument intended to be used for the<br>quantitative in vitro measurement of oxygen<br>saturation, haemoglobin derivatives and<br>other calculated haemoximetry parameters<br>in a whole blood specimen.  |
| 26         |          | Erthrocyte<br>sedimentation<br>rate (ESR)<br>analyser                       | В | An instrument intended to be used to<br>determine the erythrocyte sedimentation<br>rate (ESR) of red blood cells in an<br>anticoagulated whole blood specimen.   |
| 27         |          | Flow cytometry<br>analyser  | В | An instrument intended to be used to count,<br>examine and/or sort cells or microscopic<br>particles in a clinical specimen.   |
| 28         |          | Heparin analyser  | В | A device that measures heparin concentration in blood samples.   |
| 29         |          | Osmotic fragility<br>analyser   | В | An instrument intended to be used for the determination of the osmotic fragility of red blood cells in a whole blood specimen.   |
| 30         |          | Reticulocyte<br>analyser  | В | An instrument intended to be used for the qualitative and/or quantitative in vitro determination of reticulocytes, or immature red blood cells in a clinical specimen.   |
| 31         |          | Blood gas<br>analyser   | С | An instrument intended to be used for the<br>quantitative in vitro measurement of blood<br>pH, partial pressure of oxygen (pO2) and/or<br>partial pressure of carbon dioxide (pCO2),<br>and the calculation of other blood gas<br>parameters in a clinical specimen. |
| 32         |          | Haemoglobin<br>analyser   | В | An instrument intended to be used to determine the concentration of haemoglobin in a clinical specimen.  |

| <b>Sr.</b><br><b>No.</b><br>33 | Category   | Name of the<br>In-Vitro<br>Diagnostic<br>Medical Devices<br>(IVD Analyzers) |   | Intended use An instrument intended to be used for the   |
|--------------------------------|------------|---|---|--|
|                                |            | aggregation<br>analyser   |   | qualitative and/or quantitative in vitro<br>examination of platelet function in a clinical<br>specimen, by inducing platelet aggregation<br>through the addition of platelet aggregating<br>agents.  |
| 34                             | Immunology | Densitometry<br>analyser  | В | An instrument intended to be used for the<br>qualitative and/or quantitative in vitro<br>determination of the staining pattern<br>intensity on film, acetate or other composite<br>medium to separate and/or visualize the<br>individual components of a clinical<br>specimen. |
| 35                             |            | Enzyme<br>immunoassay<br>(EIA) analyser                                     | С | An instrument intended to be used for the<br>qualitative and/or quantitative in vitro<br>determination of chemical and/or biological<br>markers, in a clinical specimen, using an<br>immunological method.   |
| 36                             |            | Fluorescent<br>immunoassay<br>analyser                                      | С | An instrument intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen.   |
| 37                             |            | Immunology<br>analyzer  | С | An analyzer used to identify and detect the concentration of specific substances in a sample, using immunoassay methodologies.   |
| 38                             |            | Immunofluoresce<br>nt analyser  | С | A device used to measures the volume of antigen/antibody present in the components of body fluids.   |
| 39                             |            | Microarray<br>analyser  | В | An instrument intended to be used for the in<br>vitro determination of multiple target<br>analytes in a single clinical specimen using<br>oligonucleotide capture molecules arranged<br>in a consistent pattern on a slide, chip or<br>membrane.                               |

| Sr.<br>No. | Category     | Name of the<br>In-Vitro<br>Diagnostic<br>Medical Devices<br>(IVD Analyzers) | Risk Class<br>as per<br>Part II, First<br>Schedule of<br>MDR 2017 | Intended use   |
|------------|--------------|---|---|--|
| 40         |              | Particle-counting<br>immunoassay<br>analyser                                | С   | A device for immunological measurement<br>by counting latex aggregates based on the<br>light scattering.   |
| 41         |              | Photometric<br>immunoassay<br>analyser                                      | С   | An instrument, intended to be used to scan<br>an immunoassay reagent vehicle after<br>exposure to a clinical specimen, to provide<br>a quantitative, semi-quantitative and/or<br>qualitative in vitro determination of chemical<br>substances and/or biological markers in a<br>clinical specimen, using photometry. |
| 42         | Microbiology | Antimicrobial<br>susceptibility<br>analyser                                 | В   | An instrument intended to be used for the in<br>vitro determination of an antimicrobial<br>susceptibility profile by monitoring the<br>growth rate of a microbiological organism<br>from a clinical specimen and/or culture<br>isolate when exposed to a range of<br>antimicrobials.                                 |
| 43         |              | Blood culture<br>analyser   | С   | An instrument intended to be used for the<br>qualitative and/or quantitative in vitro<br>determination of microorganism growth in a<br>blood culture preparation or other clinical<br>specimen, with or without subsequent<br>identification of the organism.  |
| 44         |              | Gene analyser   | С   | A device that analyzes the sequence<br>information of nucleic acid molecules<br>extracted from biological samples.   |
| 45         |              | Immunoturbidime<br>tric analyser  | С   | A light scattering analyzer that quantifies the<br>analytes in the body fluid by measuring the<br>light scattering intensity from the immune<br>complex generated in the reaction between<br>analyte and antibody.   |

| <b>Sr.</b><br><b>No.</b><br>46 | Category   | Name of the<br>In-Vitro<br>Diagnostic<br>Medical Devices<br>(IVD Analyzers)<br>Microorganism<br>identification | Risk Class<br>as per<br>Part II, First<br>Schedule of<br>MDR 2017<br>B | Intended use<br>An instrument intended to be used for the<br>identification of bacteria and/or yeast   |
|--------------------------------|--|--|--|--|
|                                |  | analyser   |  | isolated from clinical specimens by<br>characterizing their morphology, substrate<br>utilization and/or biochemical reactivity,<br>using growth detection technology.  |
| 47                             |  | Nucleic acid<br>amplification<br>(PCR) analyser  | D  | An instrument intended to amplify target deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) in a clinical specimen.   |
| 48                             |  | Yeast/fungi<br>identification<br>analyser  | В  | An instrument intended to be used for the<br>identification of yeast and/or fungi isolated<br>from clinical specimens by characterizing<br>their morphology, substrate utilization<br>and/or biochemical reactivity, using growth<br>detection technology.                     |
|                                |  | o Diagnostic Med   | lical Devices  |  |
| 49                             | Clinical<br>chemistry /<br>Microbiology<br>/ Toxicology    | Gas<br>chromatography<br>analyser  | В  | An instrument intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen.   |
| 50                             | Clinical<br>chemistry /<br>Microbiology<br>/<br>Hematology | Mass<br>spectrometry<br>analyser   | В  | An instrument intended to be used for the<br>qualitative and/or quantitative determination<br>of the chemical composition of a clinical<br>specimen by ionizing the specimen and<br>separating the resulting ions according to<br>mass using an electrical and magnetic field. |

| Sr.<br>No. | Category                                | Name of the<br>In-Vitro<br>Diagnostic<br>Medical Devices<br>(IVD Analyzers) |   | Intended use  |
|------------|---|---|---|---|
| 51         | Clinical<br>chemistry /<br>Immunology   | Nephelometry<br>immunoassay<br>analyser                                     | С | An instrument intended to be used for the<br>qualitative and/or quantitative in vitro<br>determination of chemical and/or biological<br>markers in a clinical specimen using an<br>immunological method which utilizes a<br>nephelometric detection system. |
| 52         | Gastroenter<br>ology and<br>Urology     | Faecal occult<br>blood<br>immunoassay<br>analyser                           | В | An instrument intended to be used for the<br>qualitative and/or quantitative in vitro<br>determination of faecal occult blood, using<br>an immunological method to detect or<br>measure haemoglobin in a clinical stool<br>(faeces) specimen.               |
| 53         | Obstetrical<br>and<br>Gynecologic<br>al | Spermatozoa/se<br>men analyser  | В | An instrument intended to be used for the<br>qualitative and/or quantitative in vitro<br>examination of a semen specimen to<br>assess volume, spermatozoa concentration,<br>motility and/or morphological<br>characteristics.                               |

# CATEGORY: IVD INSTRUMENT

## **TOTAL NO. OF IVD INSTRUMENT:**

18 Nos.

|            | List of In-Vitro Diagnostic Medical Devices (IVD Instruments)<br>under provisions of sub-rule (2) rule 4 of the Medical Devices Rules, 2017 |  |   |  |  |
|------------|---|--|---|--|--|
| Sr.<br>No. | Name of the<br>In-Vitro<br>Diagnostic<br>Medical<br>Devices<br>(IVD<br>Instruments)   | Risk Class<br>as per<br>Part II, First<br>Schedule<br>of MDR<br>2017 | Intended use  |  |  |
| 1          | Blood smear<br>cassette   | A  | A device designed to be inserted into an automated<br>microscope slide processing instrument to create a blood<br>smear on a microscope examination slide for subsequent<br>staining and/or microscopic analysis.   |  |  |
| 2          | Blood smear<br>instrument   | A  | A manual laboratory instrument intended to be used to create a blood smear on a microscope examination slide for subsequent staining and/or microscopic analysis.   |  |  |
| 3          | Blood tube mixer  | A  | An instrument intended to be used for the mixing of<br>blood or other biological fluids contained in blood tubes<br>or other similar specimen receptacles using continuous<br>motion or agitation.  |  |  |
| 4          | Cell washer   | A  | An instrument intended to be used to separate red blood<br>cells from whole blood and wash the intact red blood<br>cells, to remove plasma, debris and/or any other<br>extraneous material so they are free from interfering<br>substances and suitable for use in subsequent in vitro<br>clinical testing. |  |  |
| 5          | Colony counter  | В  | A device designed to count bacterial colonies in a culture.   |  |  |

|    |   | A |   |
|----|---|---|---|
| 6  | Inoculating loop  |   | A device intended to be used to transfer and spread<br>inoculum from a clinical specimen and/or culture isolate<br>into a culture medium for subsequent in vitro diagnostic<br>processingand/or testing.  |
| 7  | Magnetic particle<br>separation<br>instrument                   | С | An instrument intended to be used for the automated pre-<br>analytical extraction of specific molecules from a clinical<br>specimen using magnetic particle separation techniques.  |
| 8  | Microbial<br>incubator/imaging<br>system                        | A | A device intended to provide ideal conditions for<br>microbial growth with an incubator, and to capture digital<br>images of the specimens contained within the incubator<br>at specified time intervals.   |
| 9  | Microplate seal<br>roller                                       | A | A manually-operated device intended to firmly apply a seal to a microplate.   |
| 10 | Microplate washer   | A | An instrument intended to be used for washing microplates.  |
| 11 | Microscope slide<br>coverslipper                                | A | An instrument intended to be used to apply a coverslip<br>over a microscope examination slide to protect the<br>fixed/stained specimen from mechanical forces or<br>environmental exposure prior to microscopic examination<br>and/or long-term storage of the slide.                       |
| 12 | Microscope slide<br>hybridization/den<br>aturation<br>incubator | A | An instrument intended to be used for the incubation of<br>microscope slides for the denaturation and/or<br>hybridization of a clinical specimen as part of an in situ<br>hybridization (ISH) and/or fluorescence in situ<br>hybridisation (EISH) protocol                                  |
| 13 | Microscope slide<br>maker/stainer                               | A | An instrument intended to be used to prepare, transfer or<br>fix blood, tissue or other clinical specimens onto<br>microscope examination slides, and then stain the slides<br>using one or more biological or cytochemical staining<br>solutions in preparation for subsequent microscopic |

| 14 | Microscope slide<br>washer                          | A | An instrument intended to be used for washing<br>microscope slides by applying a flow of washing solution<br>as part of the processing steps required to perform an in<br>vitro diagnostic assay.   |
|----|---|---|---|
| 15 | Nucleic acid<br>sample<br>preparation<br>instrument | С | An instrument intended to be used for the pre-analytical preparation of samples for downstream nucleic acid analysis.   |
| 16 | Slide-mounted-<br>tissue dissection<br>system       | В | An assembly of devices designed to be used for dissection<br>of microscope-slide-mounted tissue specimens under<br>digital image guidance, allowing the user to digitally<br>preselect the target dissection area with high precision.<br>Excised tissues are suctioned into a sample tube for<br>subsequent histopathology analysis.                                 |
| 17 | Specimen<br>processing<br>instrument                | В | An instrument or platform intended to be used for the<br>automated pre-analytical preparation of a clinical<br>specimen (excluding specimens for microbial culture),<br>which may include the sampling, diluting, and/or<br>aliquoting of clinical specimens and/or any post-analytical<br>processing required, including labelling, storage and/or<br>location data. |
| 18 | Blood component<br>separator                        | В | A device designed for the separation of whole blood or<br>previously centrifuged blood into components for further<br>processing or storage. It is typically used in a blood bank<br>or transfusion centre, and is not donor or patient<br>connected.   |

## CATEGORY: IVD SOFTWARE

## **TOTAL NO. OF IVD SOFTWARE:**

09 Nos.

|            | List of In-Vitro Diagnostic Medical Devices (IVD Software)<br>under provisions of sub-rule (2) rule 4 of the Medical Devices Rules, 2017 |   |  |  |  |  |
|------------|--|---|--|--|--|--|
| Sr.<br>No. | Name of the<br>In-Vitro Diagnostic<br>Medical Devices<br>(IVD Software)  | Risk Class as<br>per<br>Part II, First<br>Schedule of<br>MDR 2017 | Intended use   |  |  |  |
| 1          | Cancer cell<br>marker/morphology<br>image-analysis software  | С   | A software program with specific image<br>analysis algorithms intended to be used in a<br>digital pathology laboratory to assist in the<br>analysis of immunohistochemically- or<br>histologically-stained clinical specimens for<br>the quantitative detection of cell markers or<br>changes in tissue architecture and/or cell<br>morphological/physiological characteristics<br>associated with any type of cancer,<br>performed during in vitro diagnostic (IVD)<br>testing. |  |  |  |
| 2          | Cancer risk assessment<br>interpretive software  | С   | An interpretive software program intended to<br>be used in the assessment of risk for<br>developing cancer, by using IVD results of<br>the qualitative and/or quantitative detection of<br>one or multiple cancer-specific biomarkers in<br>a clinical specimen.   |  |  |  |
| 3          | Cardiovascular<br>risk/probability<br>assessment interpretive<br>software  | С   | An interpretive software program intended to<br>be used in the assessment of risk/probability<br>for having a cardiovascular condition or<br>event, by using results of the<br>qualitative/quantitative clinical specimen in<br>vitro diagnostic (IVD) tests.  |  |  |  |

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| 4 | Clinical laboratory<br>information system<br>application software         | С | An application software program, used as or<br>in an information system to electronically<br>receive, collect, store, manage, assist in<br>analysis of, display, output, and distribute<br>data, within or between healthcare facilities,<br>to support the administrative and clinical<br>activities associated with clinical laboratory<br>services and facilities.               |
|---|---|---|---|
| 5 | Congenital<br>defect/syndrome risk<br>assessment interpretive<br>software | С | An interpretive software program intended to<br>be used in the assessment of risk for the<br>presence of a congenital medical defect<br>and/or condition of a foetus. in vitro<br>diagnostic (IVD) results of various<br>maternal/foetal biochemical, hormonal and/or<br>ultrasound markers.  |
| 6 | Human genomic<br>analysis interpretive<br>software                        | С | An interpretive software program intended to<br>be used for the analysis and visualization of<br>human genome data from in vitro diagnostic<br>(IVD) results obtained through molecular<br>genetic testing. It provides predictive and/or<br>diagnostic information used in the<br>assessment of adverse health condition risk,<br>disease prevention, and/or health<br>management. |
| 7 | Laboratory<br>instrument/analyser<br>application software                 | С | A software program intended to be used with<br>an in vitro diagnostic instrument/analyser or a<br>data management device connected to the<br>IVD instrument/analyser, to facilitate user-<br>controlled device function and/or data<br>processing, display, or communication.   |

| 8 | Microbial identification<br>interpretive software        | С | An application software program intended to<br>be used to identify microbial species<br>(bacterial, fungal) using results from<br>microbial cultures and laboratory biochemical<br>tests. Results from an in vitro diagnostic<br>medical device (IVD) are input and the<br>name(s), and reliability of possible microbial<br>species returned. It is intended for use in a<br>microbiology laboratory.  |
|---|--|---|---|
| 9 | Osteoporosis risk<br>assessment interpretive<br>software | С | An interpretive software program intended to<br>be used in the assessment of risk for<br>developing osteoporosis. This interpretive<br>software program typically combines patient<br>demographics and the in vitro diagnostic<br>(IVD) results of the qualitative and/or<br>quantitative detection of one or multiple<br>proteins in a tissue sample to establish an<br>individual risk score that may be used to<br>guide patient management. |