Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No. IVD/Misc/196/2020 Date: 25 OCT 2023

Subject: Classification of *In-vitro* Diagnostic Medical Devices under the provisions of Medical Devices Rules, 2017 - Regarding.

Safety, quality and performance of Medical Devices and In-vitro Diagnostic Medical Devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules, made there under. For the regulation of Medical Devices and In-vitro Diagnostic Medical Devices with respect to the import, manufacture, clinical investigation, clinical performance evaluation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78(E) dated 31.01.2017 which is already implemented from 01.01.2018.

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the in-vitro Diagnostic Medical Devices based on the intended use, risk associated with the device and other parameters specified in the First Schedule.

Updated list of In-vitro Diagnostics Medical Devices placed at Annexure A (*Updated*), Annexure B (*Updated*), Annexure C, Annexure D (*added*), Annexure E (*added*) is subjected to the followings:

1. General intended use given against each of the device is for guidance to the applicants who intends to furnish application of import or manufacture of medical Devices under the provisions of Medical Devices Rules, 2017. However, as device may have specified intended use as specified by its manufacturer.

2. This list is dynamic and is subjected to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General of India

To,

CDSCO Website

Annexure A (*Updated*)

File No. IVD/Misc/196/2020
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

List of In-Vitro Diagnostic Medical Devices (IVD Analyzers) under provisions of sub-rule (2) rule 4 of the Medical Devices Rules, 2017

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
1	Clinical chemistry	Alcohol body-fluid analyser	A	An analyzer (other than near-patient testing) intended to determine the concentration of alcohol in a body-fluid specimen. It is intended for in-vitro diagnostic use.
			C	An analyzer intended to be used for near-patient testing to determine the concentration of alcohol in a body-fluid specimen. It is intended for in-vitro diagnostic use.
2		Amino acid analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of individual amino acids in a protein sample obtained from a clinical specimen. It is intended for in-vitro diagnostic use.
3		Bilirubinometry analyser	A	A device (other than near-patient testing) that measures directly or indirectly the bilirubin concentration in blood or other samples. It is intended for in-vitro diagnostic use.
			C	A device intended to be used for near-patient testing that measure directly or indirectly the bilirubin concentration in blood or other samples. It is intended for in-vitro diagnostic use.
4		Catecholamines analyser	A	A device that measures catecholamine concentration in biological samples. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
5	Clinical chemistry	Chemiluminescent immunoassay analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen. It is intended for in-vitro diagnostic use.
6		Chloride coulometric titration analyser	A	An analyzer intended to be used for the quantitative measurement of chloride in a clinical specimen using a coulometric titration. It is intended for in-vitro diagnostic use.
7		Cholesterol analyser	A	A device that measures the cholesterol in serum/whole blood. It is intended for in-vitro diagnostic use.
8		Clinical chemistry analyser	A	An analyzer intended to be used for the qualitative and/or quantitative determination of one or multiple clinical chemistry analytes in a clinical specimen. It is intended for in-vitro diagnostic use.
9		Creatinine analyser	A	A device that measures creatinine concentration in urine or serum sample. It is intended for in-vitro diagnostic use.
10		Enzyme analyser	A	A device that measures the enzymatic activity of the sample for diagnosis. It is intended for in-vitro diagnostic use.
11		Glycated haemoglobin (HbA1C) analyser	A	An analyzer intended to be used for the quantitative measurement of glycated haemoglobin (HbA1c) in a clinical specimen. It is intended for in-vitro diagnostic use.
12		High performance liquid chromatography analyser	A	An analyzer designed to use high performance liquid chromatography (HPLC) for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen. It is intended for in-vitro diagnostic use.
13		Identification and Antibiotic susceptibility analyser	A	A device that identifies infectious/ pathogenic microorganisms by photometry such as absorption, fluorescence and luminescence, and measures the susceptibility to therapeutic drugs. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
14	Clinical chemistry	Ion-selective analyser	A	An analyzer intended to be used for the quantitative measurement of electrolytes and/or other ions in a clinical specimen. It is intended for in-vitro diagnostic use.
15		Lactate analyser	A	An analyzer used to determine the concentration of lactate in various body fluids using the lactate oxidase fixation electrode. It is intended for in-vitro diagnostic use.
16		Lipid profile analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of lipid profile analytes in a clinical specimen. It is intended for in-vitro diagnostic use.
17		Nitrogen body-fluid-sample analyser	A	An analyzer used to analyse the nitrogen (N2) content in a body fluid. It is intended for in-vitro diagnostic use.
18		Protein analyser	A	A device used to measure concentration and to identify specific proteins present in a clinical specimen. It is intended for in-vitro diagnostic use.
19		Radioimmunoassay analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen using an immunological method which utilizes a radiometric detection system to detect the presence of immune complexes labelled using a radioisotope. It is intended for in-vitro diagnostic use.
20		Urine analyser	A	An analyzer (other than near-patient testing) intended to be used for the qualitative and/or quantitative in vitro determination of various chemical and cellular constituents of a clinical urine specimen. It is intended for in-vitro diagnostic use.
			C	An analyzer intended to be used for near-patient testing for the qualitative and/or quantitative in vitro determination of various chemical and cellular constituents of a clinical urine specimen. It is intended for in-vitro diagnostic use.
21	Clinical chemistry	Biochemistry Analyzer	A	An analyzer intended for measuring and analyzing various biologic and chemical elements of human body fluid. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
22		Breath-alcohol test system	A	A device intended to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.
23		Nitric oxide breath analyzer	B	A device intended to measure fractional nitric oxide in human breath. Measurement of changes in fractional nitric oxide concentration in expired breath aids in evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to establish clinical and laboratory assessments of asthma. It is intended for in-vitro diagnostic use.
24		Osmolality test system	A	A device intended to measure ionic and non-ionic solute concentration in body fluids, such as serum and urine. Osmolality measurement is used as an adjunct to other tests in the evaluation of a variety of diseases, including kidney diseases (e.g., chronic progressive renal failure), diabetes insipidus, other endocrine and metabolic disorders, and fluid imbalances. It is intended for in-vitro diagnostic use.
25		Osmometer	A	A device intended to measure the osmotic pressure of body fluids. Measurements obtained by this device are used in the diagnosis and treatment of body fluid disorders. It is intended for in-vitro diagnostic use.
26		Plasma oncometer	A	A device intended to measure plasma oncotic pressure, which is that portion of the total plasma osmotic pressure contributed by protein and other molecules too large to pass through a specified semipermeable membrane. Because variations in plasma oncotic pressure are indications of certain disorders, measurements of the variations are useful in the diagnosis and treatment of these disorders. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
27		Refractometer	A	A device intended to determine the amount of solute in a solution by measuring the index of refraction (the ratio of the velocity of light in a vacuum to the velocity of light in the solution). The index of refraction is used to measure the concentration of certain analytes (solutes), such a plasma total proteins and urinary total solids. Measurements obtained by this device are used in the in-vitro diagnosis and treatment of certain conditions.
28		Urea Breath Analyzer	A	An analyzer intended for the use in the detection of urease (using breath sample) associated with H. pylori in the human stomach and is indicated as an aid in the initial diagnosis of H. pylori infection. It is intended for in-vitro diagnostic use.
29		Viscosimetric analyser	A	A device that measures the resistance of fluid against the flow by intermolecular force. It is also used for the analysis of whole blood, serum or plasma. It is intended for in-vitro diagnostic use.
30	Other Clinical chemistry analyser	Other Clinical chemistry analyser (other than near patient testing)	A	
31		Other Clinical chemistry analyser (intended to be used near patient testing)	C	
32	Hematology	ABO/Rh(D) blood grouping analyser	A	A lab based analyzer (other than near-patient testing) intended to be used to perform blood group testing to determine the ABO and Rh(D) status of clinical specimens. It is intended for in-vitro diagnostic use.
			D	An analyzer (for near-patient testing) intended to be used to perform blood group testing to determine the ABO and Rh(D) status of clinical specimens. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
33		Blood cell count analyser	A	A device that quantifies the formed elements in the blood (i.e., erythrocytes, leukocytes, and platelets) by electro impedance, optical scattering or dye binding. It is intended for in-vitro diagnostic use.
34		Blood coagulation analyser	A	An analyzer (other than near-patient testing) 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. It is intended for in-vitro diagnostic use.
			C	An analyzer intended to be used for near-patient testing for the qualitative and/or quantitative in vitro determination of one or multiple coagulation components involved in haemostasis in a clinical specimen. It is intended for in-vitro diagnostic use.
35		Blood group/antibody screening analyser	A	An analyzer intended to be used to perform pre-transfusion blood group testing, red cell antibody screening/identification and/or red cell phenotyping of clinical specimens or donor specimens in order to determine suitability for transfusion or transplantation. It is intended for in-vitro diagnostic use.
36		Co-oximetry analyser	B	An analyzer intended to be used for the quantitative in vitro measurement of oxygen saturation, haemoglobin derivatives and other calculated haemoximetry parameters in a whole blood specimen. It is intended for in-vitro diagnostic use.
37		Erthrocyte sedimentation rate (ESR) analyser	A	An analyzer intended to be used to determine the erythrocyte sedimentation rate (ESR) of red blood cells in an anticoagulated whole blood specimen. It is intended for in-vitro diagnostic use.
38		Flow cytometry analyser	A	An analyzer intended to be used to count, examine and/or sort cells or microscopic particles in a clinical specimen. It is intended for in-vitro diagnostic use.
39		Heparin analyser	A	A device that measures heparin concentration in blood samples. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
40		Osmotic fragility analyser	A	An analyzer intended to be used for the determination of the osmotic fragility of red blood cells in a whole blood specimen. It is intended for in-vitro diagnostic use.
41		Reticulocyte analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of reticulocytes, or immature red blood cells in a clinical specimen. It is intended for in-vitro diagnostic use.
42		Blood gas analyser	A	An analyzer (other than near-patient testing) intended to be used for the quantitative in vitro measurement of blood pH, partial pressure of oxygen (pO2) and/or partial pressure of carbon dioxide (pCO2), and the calculation of other blood gas parameters in a clinical specimen. It is intended for in-vitro diagnostic use.
			C	An analyzer intended to be used for near-patient testing for the quantitative in vitro measurement of blood pH, partial pressure of oxygen (pO2) and/or partial pressure of carbon dioxide (pCO2), and the calculation of other blood gas parameters in a clinical specimen. It is intended for in-vitro diagnostic use.
43		Haemoglobin analyser	A	An analyzer intended to be used to determine the concentration of haemoglobin in a clinical specimen. It is intended for in-vitro diagnostic use.
44		Hematology Analyzer	A	An analyzer intended to analyze in-vitro samples of whole blood to provide complete blood count, leucocyte differential count, classify and/or enumerate various parameters using the impedance and spectrophotometry techniques. It is intended for in-vitro diagnostic use.
45		Thromboelastrogram (TEG) Hemostasis Analyzer	A	An analyzer intended to provide a quantitative and/or qualitative indication of the hemostasis state of a blood sample by monitoring, measuring, analyzing and reporting hemostasis parameter information, in order to assist in the assessment of patient clinical hemostasis conditions. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
46		Platelet aggregation analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro examination of platelet function in a clinical specimen, by inducing platelet aggregation through the addition of platelet aggregating agents. It is intended for in-vitro diagnostic use.
47	Other hematology analyser	Other hematology analyser (other than near patient testing)	A	
48		Other hematology analyser (intended to be used near patient testing)	C	
49	Immunology	Densitometry analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of the staining pattern intensity on film, acetate or other composite medium to separate and/or visualize the individual components of a clinical specimen. It is intended for in-vitro diagnostic use.
50		Enzyme immunoassay (EIA) analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers, in a clinical specimen, using an immunological method. It is intended for in-vitro diagnostic use.
51		Fluorescent immunoassay analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
52		Immunology analyzer	A	An analyzer used to identify and detect the concentration of specific substances in a sample, using immunoassay methodologies. It is intended for in-vitro diagnostic use.
53		Immunofluorescent analyser	A	A device used to measures the volume of antigen/antibody present in the components of body fluids. It is intended for in-vitro diagnostic use.
54		Microarray analyser	A	An analyzer intended to be used for the in vitro determination of multiple target analytes in a single clinical specimen using oligonucleotide capture molecules arranged in a consistent pattern on a slide, chip or membrane. It is intended for in-vitro diagnostic use.
55	Immunology	Particle-counting immunoassay analyser	A	A device for immunological measurement by counting latex aggregates based on the light scattering. It is intended for in-vitro diagnostic use.
56		Photometric immunoassay analyser	A	An analyzer, intended to be used to scan an immunoassay reagent vehicle after exposure to a clinical specimen, to provide a quantitative, semi-quantitative and/or qualitative in vitro determination of chemical substances and/or biological markers in a clinical specimen, using photometry. It is intended for in-vitro diagnostic use.
57	Microbiology	Antimicrobial susceptibility analyser	A	An analyzer intended to be used for the in vitro determination of an antimicrobial susceptibility profile by monitoring the growth rate of a microbiological organism from a clinical specimen and/or culture isolate when exposed to a range of antimicrobials. It is intended for in-vitro diagnostic use.
58		Blood culture analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of microorganism growth in a blood culture preparation or other clinical specimen, with or without subsequent identification of the organism. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
59		Gene analyser	A	A device that analyzes the sequence information of nucleic acid molecules extracted from biological samples. It is intended for in-vitro diagnostic use.
60		Immunoturbidimetric analyser	A	A light scattering analyzer that quantifies the analytes in the body fluid by measuring the light scattering intensity from the immune complex generated in the reaction between analyte and antibody. It is intended for in-vitro diagnostic use.
61	Microbiology	Microorganism identification analyser	A	An analyzer intended to be used for the identification of bacteria and/or yeast isolated from clinical specimens by characterizing their morphology, substrate utilization and/or biochemical reactivity, using growth detection technology. It is intended for in-vitro diagnostic use.
62		Nucleic acid amplification (PCR) analyser	A	An analyzer intended to amplify target deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) in a clinical specimen. It is intended for in-vitro diagnostic use.
63		Yeast/fungi identification analyser	A	An analyzer intended to be used for the identification of yeast and/or fungi isolated from clinical specimens by characterizing their morphology, substrate utilization and/or biochemical reactivity, using growth detection technology. . It is intended for in-vitro diagnostic use.
64	Clinical chemistry / Microbiology / Toxicology	Gas chromatography analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen. It is intended for in-vitro diagnostic use.
65	Clinical chemistry / Microbiology/ Hematology	Mass spectrometry analyser	A	An analyzer intended to be used for the qualitative and/or quantitative determination of the chemical composition of a clinical specimen by ionizing the specimen and separating the resulting ions according to mass using an electrical and magnetic field. It is intended for in-vitro diagnostic use.

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices (IVD Analyzers)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
66	Clinical chemistry / Immunology	Nephelometry immunoassay analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of chemical and/or biological markers in a clinical specimen using an immunological method which utilizes a nephelometric detection system. It is intended for in-vitro diagnostic use.
67	Gastroenterology and Urology	Faecal occult blood immunoassay analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of faecal occult blood, using an immunological method to detect or measure haemoglobin in a clinical stool (faeces) specimen. It is intended for in-vitro diagnostic use.
68	Obstetrical and Gynecological	Spermatozoa/semen analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro examination of a semen specimen to assess volume, spermatozoa concentration, motility and/or morphological characteristics. It is intended for in-vitro diagnostic use.
69	Immunology	Automated indirect immunofluorescence microscope	A	A device that acquires, analyzes (results), stores, and displays digital images of indirect immunofluorescent slides. It is intended to be used as an aid in the determination of antibody status in clinical samples. It is intended for in-vitro diagnostic use.
70	Immunology	ELISA Plate Reader	A	An analyzer intended for in vitro diagnostic use to measure radiant energy emitted, transmitted, absorbed, or reflected under controlled conditions and interpret ELISA test results. It is intended for in-vitro diagnostic use.
71	Microbiology	Microscope	A	A device intended to enlarge images of specimens, preparations and/or cultures (to gain its physiological or morphological information) for in-vitro diagnostic use.
72	Toxicology	Lead test analyser	A	A device intended to measure lead, a heavy metal, in blood and urine. Measurements obtained by this device are used in the diagnosis and treatment of lead poisoning. . It is intended for in-vitro diagnostic use.

Annexure B (*Updated*)

File No. IVD/Misc/196/2020
Drugs Controller General (India)
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FDA Bhawan, Kotla Road, New Delhi

List of In-Vitro Diagnostic Medical Devices (IVD Instruments) under provisions of sub-rule (2) rule 4 of the Medical Devices Rules, 2017

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
1	Blood smear cassette	A	A device designed to be inserted into an automated microscope slide processing instrument to create a blood smear on a microscope examination slide for subsequent staining and/or microscopic analysis. It is intended to be used for an in vitro diagnostic procedure.
2	Blood smear 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. It is intended to be used for an in vitro diagnostic procedure.
3	Blood tube mixer	A	An instrument intended to be used for the mixing of blood or other biological fluids contained in blood tubes or other similar specimen receptacles using continuous motion or agitation. It is intended to be used for an in vitro diagnostic procedure.
4	Blood component separator	A	A device designed for the separation of whole blood or previously centrifuged blood into components for further processing or storage. It is typically used for an in vitro diagnostic procedure, and is not donor or patient connected.

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
5	Cell washer	A	An instrument intended to be used to separate red blood cells from whole blood and wash the intact red blood cells, to remove plasma, debris and/or any other extraneous material so they are free from interfering substances. It is intended to be used for an in vitro diagnostic procedure.
6	Colony counter	A	A device designed to count bacterial coloniesin a culture. It is intended to be used for an in vitro diagnostic procedure.
7	Inoculating loop	A	A device intended to be used to transfer and spread inoculum from a clinical specimen and/or culture isolate into a culture medium for subsequent in vitro diagnostic processing and/or testing.
8	Magnetic particle separation instrument	A	An instrument intended to be used for the automated pre-analytical extraction of specific molecules from a clinical specimen using magnetic particle separation techniques. It is intended to be used for an in vitro diagnostic procedure.
9	Microbial incubator/imaging system	A	A device intended to provide ideal conditions for microbial growth with an incubator, and to capture digital images of the specimens contained within the incubator at specified time intervals. It is intended to be used for an in vitro diagnostic procedure.
10	Microplate seal roller	A	A manually-operated device intended to firmly apply a seal to a microplate. It is intended to be used for an in vitro diagnostic procedure.

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
11	Microplate washer	A	An instrument intended to be used for washing microplates. It is intended to be used for an in vitro diagnostic procedure.
12	Microscope slide coverslipper	A	An instrument intended to be used to apply a coverslip over a microscope examination slide to protect the fixed/stained specimen from mechanical forces or environmental exposure prior to microscopic examination and/or long-term storage of the slide. It is intended to be used for an in vitro diagnostic procedure.
13	Microscope slide hybridization/ denaturation incubator	A	An instrument intended to be used for the incubation of microscope slides for the denaturation and/or hybridization of a clinical specimen as part of an in situ hybridization (ISH) and/or fluorescence in situ hybridisation (FISH) protocol. It is intended to be used for an in vitro diagnostic procedure.
14	Microscope slide maker/stainer	A	An instrument intended to be used to prepare, transfer or fix blood, tissue or other clinical specimens onto microscope examination slides, and then stain the slides using one or more biological or cytochemical staining solutions in preparation for subsequent microscopic analysis. It is intended to be used for an in vitro diagnostic procedure.
15	Microscope slide washer	A	An instrument intended to be used for washing microscope slides by applying a flow of washing solution as part of the processing steps required to perform an in vitro diagnostic assay. It is intended to be used for an in vitro diagnostic procedure.

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
16	Nucleic acid sample preparation instrument	A	An instrument intended to be used for the pre-analytical preparation of samples for downstream nucleic acid analysis. It is intended to be used for an in vitro diagnostic procedure.
17	Slide-mounted-tissue dissection system	A	An assembly of devices designed to be used for dissection of microscope-slide-mounted tissue specimens under digital image guidance, allowing the user to digitally preselect the target dissection area with high precision. Excised tissues are suctioned into a sample tube for subsequent histopathology analysis. It is intended to be used for an in vitro diagnostic procedure.
18	Specimen processing instrument	A	An instrument or platform intended to be used for the automated pre-analytical preparation of a clinical specimen (excluding specimens for microbial culture), which may include the sampling, diluting, and/or aliquoting of clinical specimens and/or any post-analytical processing required, including labelling, storage and/or location data. It is intended to be used for an in vitro diagnostic procedure.
19	Cell-freezing apparatus	A	A device used to freeze human red blood cells. It is intended to be used for an in vitro diagnostic procedure.
20	Centrifuge	A	An instrument intended to separate, sediment, spin down aqueous solutions and solvent suspensions of differing densities in compatible sample containers. It is intended to be used for an in vitro diagnostic procedure.

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
21	Cold plate	A	A device intended for chilling and blocking out of histological tissue samples in paraffin blocks. It is intended to be used for an in vitro diagnostic procedure.
22	Electrophoresis apparatus	A	An instrument intended to separate molecules or particles, including plasma proteins, lipoproteins, enzymes, and hemoglobulins on the basis of their net charge in specified buffered media. This device is used in conjunction with certain materials to measure a variety of analytes as an aid in the diagnosis and treatment of certain disorders. It is intended to be used for an in vitro diagnostic procedure.
23	Hot plate	A	A device designed with heating plate with high heat output and precise temperature control, suitable for flattening and drying cut histological tissue specimens in molten paraffin. It is intended to be used for an in vitro diagnostic procedure.
24	Microscope glass slide	A	A device intended for mounting Formalin Fixed Paraffin Embedded (FFPE) tissue sections/ specimens, suitable for cellular and tissue specimen preparation for microscopic analysis intended to be used for an in vitro diagnostic procedure.
25	Paraffin Dispenser	A	Paraffin or Wax dispenser is an instrument that melts the solid paraffin, maintains it in its molten form and dispenses it as and when required. The dispenser is separately heated to maintain the same temperature as the paraffin reservoir. It is used in Histopathology, Forensic Medicine and Anatomy Lab, where wax embedded moulds or blocks are prepared for in vitro diagnostic procedure.

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
26	Paraffin flotation bath	A	A device designed for use as a heated, distilled water floating out bath for the manipulation and location of paraffin wax sections onto glass slides, it is used for in vitro diagnostic procedure.
27	Pipette/ Micropipette	A	An instrument designed and constructed for accurate and precise liquid handling, specifically intended by the manufacturer to be used for in vitro diagnostic examinations/procedures. It is intended to dispense liquid (sample/specimen/buffer solutions) in appropriate volume range in combination with matching pipette tips.
28	Tissue embedding system	A	An instrument meant for embedding histological tissue specimens in molten paraffin for use in pathology laboratories. It is intended to be used for an in vitro diagnostic procedure.
29	Any other instrument intended for diagnostic purpose	A	

Annexure C

File No. IVD/Misc/196/2020
Drugs Controller General (India)
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FDA Bhawan, Kotla Road, New Delhi

List of In-Vitro Diagnostic Medical Devices (IVD Software) under provisions of sub-rule (2) rule 4 of the Medical Devices Rules, 2017

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

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Software)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
5	Human genomic analysis interpretive software	C	An interpretive software program intended to be used for the analysis and visualization of human genome data from in vitro diagnostic (IVD) results obtained through molecular genetic testing. It provides predictive and/or diagnostic information used in the assessment of adverse health condition risk, disease prevention, and/or health management.
6	Laboratory instrument/analyser application software	A	A software program intended to be used with an in vitro diagnostic instrument/analyser or a data management device connected to the IVD instrument/analyser, to facilitate user-controlled device function.
7	Microbial identification interpretive software	A	An application software program intended to be used to identify microbial species (bacterial, fungal) using results from microbial cultures and laboratory biochemical tests. Results from an in vitro diagnostic medical device (IVD) are input and the name(s), and reliability of possible microbial species returned. It is intended for use in a microbiology laboratory.
8	Osteoporosis risk assessment interpretive software	A	An interpretive software program intended to be used in the assessment of risk for developing osteoporosis. This interpretive software program typically combines patient demographics and the in vitro diagnostic (IVD) results of the qualitative and/or quantitative detection of one or multiple proteins in a tissue sample to establish an individual risk score that may be used to guide patient management.

Note:

- Software, which drives a device or influences the use of a device, falls automatically in the same class.
- Software that is not incorporated in an *in vitro* diagnostic medical device shall be classified using the classification provisions as specified in paragraph 2 of Part II of First Schedule of Medical Devices Rules, 2017.

Annexure D (*Added*)

File No. IVD/Misc/196/2020
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

List of In-Vitro Diagnostic Medical Devices (IVD- Specimen receptacle) under provisions of sub-rule (2) rule 4 of the Medical Devices Rules, 2017

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
1	Blood Collection Tube	A	A device, whether vacuum type or not, with/without coating (coating such as EDTA, heparin, silicones, blood clot activators, inhibitors, etc.), specifically intended by its manufacturer for the primary containment of predetermined volume of blood derived from human or animal body, for the purpose of *in vitro* diagnostic examinations.
2	Sample containers	A	A device specifically intended by its manufacturer for the primary containment of specimens derived from human or animal body, for the purpose of *in vitro* diagnostic examinations.
3	Arterial Blood Gas (ABG) Sampler	A	A device (sampler/syringe) for Blood Gas Analysis (without needle) which is preheparinized, electrolyte-balanced intended for the collection of arterial blood samples and to connect with a Blood Gas Analyzer for pH, blood gas, oximetry, electrolyte and metabolite analysis. It is intended for the purpose of *in vitro* diagnostic examinations.
4	Microcuvette	A	A device intended for sample collection and to measure appropriate volume of blood (Capillary, venous and arterial whole blood) directly from the skin surface by capillary action. It is intended for the purpose of *in vitro* diagnostic examinations.

Sr. No.	Name of the In-Vitro Diagnostic Medical Devices (IVD Instruments)	Risk Class as per Part II, First Schedule of MDR 2017	Intended use
5	Other Specimen Receptacles (vacuum type or not) without needle used for the collection of Blood, Urine, Stool, Sputum, Semen, etc., for purpose of specimens collection intended for in-vitro diagnostics purpose.	A	

Annexure E(*Added*)

File No. IVD/Misc/196/2020
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

List of In-Vitro Diagnostic Medical Devices under provisions of sub-rule (2) rule 4 of the Medical Devices Rules, 2017

Sr. No.	Category	Name of the In-Vitro Diagnostic Medical Devices	Risk class as per Part –II First Schedule of MDR 2017	Intended use
1.	COVID-19 IVD	Rapid/ELISA/CLIA (Serology based)	C	Used for In-Vitro diagnosis of covid-19
		RT-PCR/LAMP (Molecular Based)	C	Used for In-Vitro diagnosis of covid-19
		Antigen Test	C	Used for In-Vitro diagnosis of covid-19
		Antigen Home test	C	Used for In-Vitro diagnosis of covid-19
2.	RNA extraction kits	Ribonucleic acid (RNA) Extraction Kits	C	Ribonucleic acid (RNA) Extraction Kits intended for specimen derived from human or animal body for In-Vitro diagnostics purpose.
3.	DNA extraction kits	Deoxyribonucleic acid (DNA) Extraction Kits	C	Deoxyribonucleic acid (DNA) Extraction Kits intended for

				specimen derived from human or animal body for In-Vitro diagnostics purpose.
4.	Viral Transport Medium (VTM)	Viral Transport Medium (VTM)	A	Viral Transport Medium (VTM) for specimen derived from Human or animal body intended for In-Vitro Diagnosis.
5	Reagents/kits for detection markers for congenital disorders	Sickle Cell IVD	C	Used for In-Vitro diagnosis of Sickle Cell