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

NOTICE

File No. IVD/Misc/196/2020

Date: 23 JUL 2021

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.

List of *In-vitro* Diagnostics Medical Devices placed at Annexure A, Annexure B and Annexure C 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. V.G. Somani)
Drugs Controller General of India

To,

CDSCO Website

Annexure A

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

Date: 23 JUL 2021

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 intended to determine the concentration of alcohol in a body-fluid specimen.
			C	An analyzer intended to be used for near-patient testing to determine the concentration of alcohol in a body-fluid specimen.
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.
3		Bilirubinometry analyser	A	A device that measures directly or indirectly the bilirubin concentration in blood or other samples.
			C	A device intended to be used for near-patient testing that measure directly or indirectly the bilirubin concentration in blood or other samples.
4		Catecholamines analyser	A	A device that measures catecholamine concentration in biological samples.
5		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.

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
6	**Clinical chemistry**	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.
7		Cholesterol analyser	A	A device that measures the cholesterol in serum/whole blood.
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.
9		Creatinine analyser	A	A device that measures creatinine concentration in urine or serum sample.
10		Enzyme analyser	A	A device that measures the enzymatic activity of the sample for diagnosis.
11		Glycated haemoglobin (HbA1C) analyser	A	An analyzer intended to be used for the quantitative measurement of glycated haemoglobin (HbA1c) in a clinical specimen.
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.
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.
14		Ion-selective analyser	A	An analyzer intended to be used for the quantitative measurement of electrolytes and/or other ions in a clinical specimen.
15		Lactate analyser	A	An analyzer used to determine the concentration of lactate in various body fluids using the lactate oxidase fixation electrode.

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
16	**Clinical chemistry**	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.
17		Nitrogen body-fluid-sample analyser	A	An analyzer used to analyse the nitrogen (N2) content in a body fluid.
18		Protein analyser	A	A device used to measure concentration and to identify specific proteins present in a clinical specimen.
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.
20		Urine analyser	A	An analyzer intended to be used for the qualitative and/or quantitative in vitro determination of various chemical and cellular constituents of a clinical urine specimen.
			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.
21	**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.
			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.

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	**Hematology**	Blood cell count analyser	A	A device that quantifies the formed elements in the blood (i. e. , erythrocytes, leukocytes, and platelets) by electroimpedance, optical scattering or dye binding.
23		Blood coagulation analyser	A	An analyzer 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.
			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.
24		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.
25		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.
26		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.
27		Flow cytometry analyser	A	An analyzer intended to be used to count, examine and/or sort cells or microscopic particles in a clinical specimen.
28		Heparin analyser	A	A device that measures heparin concentration in blood samples.

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
29	**Hematology**	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.
30		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.
31		Blood gas analyser	A	An analyzer 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.
			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.
32		Haemoglobin analyser	A	An analyzer intended to be used to determine the concentration of haemoglobin in a clinical specimen.
33		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.
34	**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.

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
35	**Immunology**	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.
36		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.
37		Immunology analyzer	A	An analyzer used to identify and detect the concentration of specific substances in a sample, using immunoassay methodologies.
38		Immunofluorescent analyser	A	A device used to measures the volume of antigen/antibody present in the components of body fluids.
39		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.
40		Particle-counting immunoassay analyser	A	A device for immunological measurement by counting latex aggregates based on the light scattering.
41		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.

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
42	**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.
43		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.
44		Gene analyser	A	A device that analyzes the sequence information of nucleic acid molecules extracted from biological samples.
45		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.
46		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.
47		Nucleic acid amplification (PCR) analyser	A	An analyzer intended to amplify target deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) in a clinical specimen.
48		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.

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
	Other In-Vitro Diagnostic Medical Devices (IVD Analyzers)			
49	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.
50	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.
51	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.
52	Gastroentero logy 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.
53	Obstetrical and Gynecologic al	Spermatozoa/seme n 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.

Annexure B

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FDA Bhawan, Kotla Road, New Delhi

Date: 23 JUL 2021

List of In-Vitro Diagnostic Medical Devices (IVD Instuments) 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.
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.
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.
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 in a blood bank or transfusion centre, and is not donor or patient connected.
5	Blood Collection Tube	A	A device, whether vacuum type or not, specifically intended for the primary containment of predetermined volume of blood derived from human or animal body.

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
6	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 and suitable for use in subsequent in vitro clinical testing.
7	Colony counter	A	A device designed to count bacterial colonies in a culture.
8	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.
9	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.
10	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.
11	Microplate seal roller	A	A manually-operated device intended to firmly apply a seal to a microplate.
12	Microplate washer	A	An instrument intended to be used for washing microplates.
13	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.

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
14	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.
15	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.
16	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.
17	Nucleic acid sample preparation instrument	A	An instrument intended to be used for the pre-analytical preparation of samples for downstream nucleic acid analysis.
18	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.
19	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.

Annexure C

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Date: 23 JUL 2021

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.