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

NOTICE

File No. 29/Misc./03/2020-DC (198) **Date: 13 SEP 2021**

Subject: Classification of medical device pertaining to Software under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices with respect to the import, manufacture, clinical investigation, 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 are to be commence 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 medical devices, based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

List of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

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

To,

1. CDSCO Website

Appendix-A

File No. 29/Misc./03/2020-DC (198)
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi
Notice

Classification of Medical Devices Pertaining to Software

S.No	Device Name	Intended Use	Risk Class
1	Continuous Glucose Monitor Retrospective Data Analysis Software	Continuous glucose monitor retrospective data analysis software is intended to analyze and correlate retrospective data from a continuous glucose monitoring device.	A
2	Continuous Glucose Monitor Secondary Display	The purpose of the continuous glucose monitor secondary display is to notify another person, the follower, of the patient's continuous glucose monitoring system sensor glucose information in real time.	B
3	Insulin Pump Secondary Display	The purpose of the insulin pump secondary display is to notify another person of the patient's insulin pump usage information in real time.	B
4	Insulin Pump Therapy Adjustment Calculator For Healthcare Professionals	An insulin pump therapy adjustment calculator for healthcare professionals is intended to recommend insulin pump therapy parameter adjustments (e.g., basal rate, insulin to carbohydrate ratios, insulin sensitivity factors) based on data from external devices, including continuous glucose monitors. The device is software with a graphical user interface.	C
5	Coronary Vascular Physiologic Simulation Software	A coronary vascular physiologic simulation software device is intended to aid in the identification of functionally significant cardiovascular disease by performing offline analysis of pre-existing imaging data to simulate blood flow in the coronary vasculature.	C
6	Multivariate Vital Signs Index	Automated calculation of a summary index (or indices) based on several individual measured vital sign inputs. Collects measured parameter inputs and automates the calculation of a summary index based on those parameters	B
7	Electrocardiograph Software for home use.	Device intended for home use which creates, analyzes, and displays electrocardiograph data, and can provide information for identifying cardiac arrhythmias.	B
8	Photoplethysmograph Analysis Software for home use.	Photoplethysmograph analysis software device for home analyzes of photoplethysmograph data and provides information for identifying irregular heart rhythms. This device is not intended to provide a clinical diagnosis.	B
9	Angiographic Coronary Vascular Physiologic Simulation Software	An angiographic coronary vascular physiologic simulation software device is intended to aid in the identification of functionally significant cardiovascular disease.	C

10	Software For Visualization Of Vascular Anatomy And Intravascular Devices	Visualization and measurement of blood vessels and intravascular devices for preoperational planning.	C
11	Orthodontic Software	The device is software that is to be used for the diagnosis and treatment planning of orthodontic patients and conditions.	C
12	Dental Abutment Design Software For Dental Laboratory	The software device is intended to aid in the restoration of chewing function by allowing a dental laboratory or dental clinician to design the patient-specific component of a dental abutment (i.e. abutment collar and abutment post) and CAM or create that component at a dental office or dental laboratory following the directions of the dental implant system.	C
13	Diagnostic Software, K-Nearest Neighbor Algorithm, Autoimmune Disease	The device is intended to suggest a systemic autoimmune disease association as an aid for differential diagnosis to be evaluated in conjunction with clinical findings and other laboratory tests.	B
14	Neuropsychiatric Interpretative Electroencephalograph Assessment Aid	Intended as an aid to provide an interpretation of the patient's neuropsychiatric condition.	C
15	Normalizing Quantitative Electroencephalograph Software	Post-hoc statistical analysis of electroencephalograph signals with comparison to a normative database for interpretation by a qualified clinical user.	C
16	Index-Generating Electroencephalograph Software	Analyze electrical activity of the brain by transformation of electroencephalograph signals into a dimensionless index number for use and interpretation by a qualified clinical user.	C
17	Source Localization Software For Electroencephalograph Or Magnetoencephalograph	Correlation of electrical activity of the brain using various neuroimaging modalities for source-localization	C
18	Automatic Event Detection Software For Polysomnograph With Electroencephalograph	Automatically mark electroencephalograph and polysomongraph signals in order to aid in identification of such events and annotation of prolonged PSG traces; Automatically calculate simple measures obtained from recorded signals (e.G. Magnitude, time, frequency and simple statistical measures of marked events); All output subject to verification by qualified clinical user	C

19	Automatic Event Detection Software For Full-Montage Electroencepha lograph	Automatically mark or identify electroencephalograph waveforms for spikes, electrographic seizures, seizure-like events in order to aid in identification of such events and help review and annotation of prolonged EEG traces; All output subject to verification by qualified clinical user	C
20	Computerized Cognitive Assessment Aid For Concussion	For use as an assessment aid in the management of concussion.	C
21	Ataxiagraph With Interpretive Software	Device used to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed and provides interpretation or clinical implication of the measurement.	A
22	Computerized Behavioral Therapy Device For Psychiatric Disorders	The device is intended to provide cognitive behavioral therapy to treat substance use disorder. The device is a software-based mobile app downloaded onto a smartphone.	C
23	Brain Injury Adjunctive Interpretive Oculomotor Assessment Aid	A traumatic brain injury eye movement assessment aid is a prescription device that uses a patients tracked eye movements to provide an interpretation of the functional condition of the patients brain.	C
24	Device, Fertility Diagnostic, Contraceptive, Software Application	Designed to monitor and provide fertility information to prevent pregnancy (contraception).	C
25	Diabetic Retinopathy Detection Device	A retinal diagnostic software device is a software device that incorporates an adaptive algorithm to evaluate ophthalmic images for diagnostic screening to identify retinal diseases or conditions.	C
26	Colon Computed Tomography System, Computer Aided Detection	To assist radiologists in the review of multi-slice computed tomography (msct) exams of the colon and highlight potential polyps that the radiologist should review.	B
27	Lung Computed Tomography System, Computer-Aided Detection	To assist radiologists in the review of multi-slice computed tomography (msct) exams of the chest and highlight potential nodules that the radiologist should review.	B
28	Chest X-Ray Computer Aided Detection	To assist radiologists in the review of chest radiographic images and highlight potential nodules that the radiologist should review.	B

29	Computer-Assisted Diagnostic Software For Lesions Suspicious For Cancer	Assist clinical users in characterizing lesions identified on acquired medical images	C
30	Radiological Computer Assisted Detection/Diagnosis Software For Fracture	A radiological computer assisted detection and diagnostic software for suspected fracture is an image processing device intended to aid in the detection, localization, and/or characterization of fracture on acquired medical images (e.g. radiography, MR, CT).	B
31	X-Ray Angiographic Imaging Based Coronary Vascular Simulation Software Device	X-ray angiographic imaging based coronary vascular simulation software device is a device that provides an image analysis tool to assess blood flow in the coronary vascular system using X-ray angiographic imaging data. And yields simulation-based metrics for certain cardiology applications which aid clinical user.	B
32	Automated Radiological Image Processing Software	To provide automated radiological image processing and artificial intelligence based analysis tools.	B
33	Image Acquisition And/Or Optimization Guided By Artificial Intelligence	A radiological acquisition and/or optimization guidance system is a device that is intended to aid in the acquisition and/or optimization of images and/or diagnostic signals.	B
34	Burn Resuscitation Decision Support Software	The burn resuscitation decision support system (BRDSS) is intended for use in prediction of hourly fluid volume during initial 24 hours of burn resuscitation. It is intended for patients who have greater than 20% total body surface area burn.	C
35	Software, Similarity Score Algorithm, Tissue Of Origin For Malignant Tumor Types	This test is intended to measure the degree of similarity between the RNA expression pattern in a patient?s fresh-frozen tumor and the RNA expression patterns in a database of tumor samples for some common malignant tumor types that were diagnosed according to then current clinical and pathological practice.	C
36	Software for peritoneal dialysis treatment	A software that performs prescription simulation of peritoneal dialysis based on the results obtained from a peritoneal function test (PFT), a peritoneal equilibration test (PET) and a body composition analyzer. It supports preparation of a dialysis treatment plan.	C
37	Software for radiation planning	A software that calculates and displays the area to be treated with radiation and the internal dose distribution based on the results obtained with CT systems etc. , and supports the radiotherapy planning.	C

38	Software for radiotherapy QAQC planning	A software that verifies the validity of the radiotherapy plan by recalculation of the dose and the MU value calculated with the radiotherapy planning system software and radiotherapy planning system.	C
39	Software for ophthalmic surgery treatment planning	A software for intended to aid ophthalmic surgical planning based on measurement of the eye prior to the surgery. It simulates surgical results.	C
40	Software for active implanted device control	A software used to transmit one or more electrical operating characteristics noninvasively to the active base unit and change the characteristics.	C
41	Information collating software for radiotherapy	A software that has function of collating the information such as irradiation parameter specified by a radiation planning software, and the condition that a radiotherapy equipment irradiates, on the occasion of the irradiation of X-ray in the radiotherapy.	C
42	Software for gene variants analysis (for cancer genome profiling)	A software for gene variants analysis which is designed to perform cancer genome profiling based on information of gene variants obtained from body tissue samples.	C
43	Supporting software for differential diagnosis with endoscopic imaging	A software, which is designed to process data obtained from an endoscopic image. The resultant data are provided for diagnostic, etc. It has functions to output numeric values and graphs based on quantitative data such as benign/malignant differentiation of lesion candidates, presenting candidates of diagnostic outcomes, and stage of disease progression.	C
44	Chairside dental CAD/CAM unit	Intended for computer-aided design (CAD) or computer-aided manufacturing (CAM) of dental restorations.	B
45	Software for using with mammography-combined diagnostic X-ray system	A software, which is designed to processes data obtained from a combined diagnostic mammography-radiography system.	B
46	Software for public thoracic and abdominal health screening diagnostic X-ray system	A software, which is designed to process data obtained from a thoracic and abdominal public health screening diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	B
47	Software for visual evoked response stimulator	A software, which is designed to process data obtained from a visual evoked response stimulator. The resultant data are provided for diagnosis, etc.	B

48	Software for auditory evoked response stimulator	A software for medical device, which is designed to process data obtained from an auditory evoked response stimulator. The resultant data are provided for diagnosis, etc.	B
49	Software for pulmonary exercise stress monitoring system	A software, which is designed to process data obtained from a pulmonary exercise stress monitoring system.	B
50	Software for ECG recorder with real-time analysis	A software, which is designed to process data obtained from an ECG recorder with real-time analysis. The resultant data are provided for diagnosis, etc.	B
51	Software for film-recorded digital radiography	A software, which is designed to process data obtained from a film-recorded digital radiography. The resultant data are provided for diagnosis, etc.	B
52	Software for dye dilution cardiac output calculator	A software, which is designed to process data obtained from a dye dilution cardiac output unit. The resultant data are provided for diagnosis, etc.	B
53	Software for urodynamic measurement system	A software, which is designed to process data obtained from a urodynamic measurement system. The resultant data are provided for diagnosis, etc.	B
54	Software for vestibular function caloric stimulator	A software, which is designed to process data obtained from a vestibular function caloric stimulator. The resultant data are provided for diagnosis, etc.	B
55	Surporting software for external fixators treatment plan	A software that analyzes information useful for bone fracture and for correction of bone deformities based on information collected from diagnostic X-ray systems, etc. or based on information entered in a therapeutic apparatus, and supports preparation of a treatment plan with external fixators.	B
56	Diagnostic supporting software for diabetes	A software that supports analysis and assessment of therapeutic effects of diabetes treatment by processeing information collected from a blood glucose meter, etc into the data related to changes or trends in blood glucose levels.	B
57	Quantitative calculation software for IGC test	A software that performs quantitative calculation of blood flow in relation to a brightness time change based on information obtained from video images of indocyanine green angiography.	B
58	Analyzing software for hemodynamics or cardiac function	A medical device program that analyzes hemodynamics or cardiac function based on information obtained from diagnostic imaging systems, etc. and uses the results for diagnosis.	B

59	Supporting software for root canal treatment	A software for medical device, which is used to support preparation of a treatment plan based on information collected from diagnostic imaging systems, etc. in the root canal treatment.	B
60	Ventilator, software	A data program designed for use in, or together with, a ventilator allowing it to function according to the intended purpose. The software can be installed, or exchanged as an upgrade.	C

Note 1 - As per clause (iii) of Part I of First Schedule of Medical Devices Rules 2017, Software, which drives or influences the use of a device, falls automatically in the same class.
Note 2 - Any add-on to the same software will be treated as same risk class.