**F. No. MED-16015(11)/1/2025-eoffice**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organisation**
**(Medical Devices Division)**

FDA Bhawan, Kotla Road,
New Delhi – 110002
Dated: - 1 APR 2025

**Notice**

**Subject: Revision of risk-based classification lists of Medical devices in the categories of Cardiovascular and Neurological-Reg.**

As per the notification vide S.O. 648(E) dated 11.02.2020, all medical devices are regulated under the Medical Devices Rules (MDR), 2017. In accordance to the MDR, 2017 Chapter II, Rule 4(3), the Central Licensing Authority needs to classify such medical devices as per risk-based approach.

In this regard, the existing classification lists in the following categories have been revisited and new entries have been added based on their classification as per the First Schedule (Part I) of the MDR, 2017:

1. Cardiovascular
2. Neurological

The draft of the classification lists is annexed for finalization. All concerned associations/stakeholders are requested to forward their comments by filling the Google form at https://forms.gle/62xF3BtXWC5pgD3TA within 30 days from the date of publication of this draft.

**(Dr. Rajeev Singh Raghuvanshi)**
**Drugs Controller General (I)**

**To: All associations/stakeholders through the CDSCO website**

**Annexure I**

**(Reference File No.: MED-16015(11)/1/2025-eoffice)**

**CATEGORIES OF MEDICAL DEVICES FOR RISK-BASED CLASSIFICATION**

| S. No. | Categories of Medical Devices |
|---|---|
| 1. | Cardiovascular |
| 2. | Neurological |

**Note:** All concerned associations/stakeholders are requested to forward their comments by filling the Google form at https://forms.gle/62xF3BtXWC5pgD3TA within 30 days from the date of publication of this draft.

# Name of Category: Cardiovascular

# Total No. of Devices: 351

## Category: Cardiovascular

| S.No. | Device name | Intended use | Risk class |
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| 1 | Active-implantable-device communicator | It is intended to communicate (e.g., via radio-frequency) with an active MR-conditional implantable device (e.g., a pulse generator) to receive information on device and/or physiologic performance, and/or to select and actuate MRI settings. | **Class D** |
| 2 | Aneroid manual sphygmomanometer | A device intended to measure blood pressure consisting of a manually inflatable cuff that fits around a limb (arm or thigh), an inflation bulb for controlling the air pressure within the cuff, an aneroid manometer, and tubing. | **Class B** |
| 3 | Aortic annuloplasty ring | A circular band intended to be implanted in the heart during open heart surgery to support an aortic valve annulus for the reconstruction and/or remodelling of an insufficient aortic valve. | **Class D** |
| 4 | Aortic bi-leaflet mechanical heart valve prosthesis | It is an artificial substitute for a natural aortic heart valve intended to be implanted during open heart surgery typically to treat acquired or congenital valvular disease. | **Class D** |
| 5 | Aortic bi-leaflet mechanical heart valve prosthesis/biologic-polymer aorta graft | An artificial substitute for a natural aortic heart valve fitted with a length of biologic-polymer blood vessel (vascular graft) intended to be implanted during open heart surgery to simultaneously replace a dysfunctional aortic heart valve and repair/replace a damaged or diseased ascending aorta (e.g., in cases of aneurysm, dissection or dilatation). | **Class D** |
| 6 | Aortic heart valve bioprosthesis | A xenograft (e.g., porcine or bovine heart valve) intended to be implanted in a patient during open heart surgery to repair or replace a dysfunctional aortic heart valve. | **Class D** |
| 7 | Aortic transcatheter heart valve bioprosthesis, stent-like framework | An implantable xenograft (e.g., bovine, porcine) intended to be used to repair/replace a stenosed and/or regurgitant aortic heart valve, or previously-implanted aortic heart valve prosthesis, and which is designed to be implanted with a catheter via transarterial access (e.g., femoral, subclavian, aortic) or transapical access while the heart is beating. | **Class D** |

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| 8 | Apexcardiograph (vibrocardiograph) | An apex cardiograph (vibrocardiograph) is a device used to amplify or condition the signal from an apex cardiographic transducer and to produce a visual display of the motion of the heart; this device also provides any excitation energy required by the transducer. | **Class B** |
| 9 | Apheresis Kit | Intended for the collection and separation of blood components | **Class C** |
| 10 | Arrhythmia Detector And Alarm (Including St-Segment Measurement And Alarm) | The arrhythmia detector and alarm device monitors an electrocardiogram and is designed to produce a visible or audible signal or alarm when atrial or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, occurs. | **Class C** |
| 11 | Arterial cannula | Inserted into an artery, commonly the radial artery, and is used during major operations and in critical care areas to measure beat-to-beat blood pressure and to draw repeated blood samples. | **Class D** |
| 12 | Arterial catheter | Intended to be used in conjunction with steerable guidewires in order to access discrete regions of the coronary and peripheral arterial vasculature. | **Class D** |
| 13 | Arteriovenous shunt | An implanted device intended to provide a passage for blood to flow between an artery typically located in an arm, and a peripheral vein, central vein or right atrium, creating a graft fistula that provides blood access for external procedures, especially haemodialysis. | **Class D** |
| 14 | Atherectomy coronary catheter | A catheter containing a rotating cutter a collecting chamber for debris, used for atherectomy and endarterectomy. | **Class D** |
| 15 | Atherectomy laser system beam guide-catheter, coronary | It is intended to be connected to an atherectomy laser system to invasively direct and deliver laser energy into the coronary arteries for the ablation of atherosclerotic plaques in completely occluded vessels. | **Class D** |
| 16 | Atherectomy peripheral catheter | Intended for use in atherectomy of the peripheral vasculature. | **Class D** |
| 17 | Automated external defibrillator, rechargeable/non-rechargeable | This electronic device is intended to automatically detect cardiac arrhythmias (ventricular fibrillation/pulseless ventricular tachycardia) in a sudden cardiac arrest (SCA) patient, after which it audibly/visually instructs an operator to enable it to activate defibrillation of the heart through application of electrical shocks to the chest surface. | **Class C** |

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| 18 | Automatic-inflation electronic sphygmomanometer, professional use, non-portable | An electronic device intended to be used in indirect (noninvasive) measurement of blood pressure using a self-contained software program that regulates automatic arm-cuff inflation and measurement cycles. In addition to systolic and diastolic pressures, it also usually displays heart rate and mean arterial pressure. | **Class B** |
| 19 | Automatic-inflation electronic sphygmomanometer, professional use, portable | A portable device designed to noninvasively measure blood pressure using a self-contained software program that regulates automatic arm/wrist-cuff inflation and measurement cycles. It typically displays current heart rate and mean arterial pressure in addition to systolic and diastolic blood pressures. | **Class B** |
| 20 | Ballistocardiograph cardiac output unit | A device used to record the body movement (toward the head and feet) caused by cardiac protrusion when blood is ejected by cardiac contraction. | **Class B** |
| 21 | Balloon dilatation vessel catheter | Intended for use in Percutaneous Transluminal Angioplasty (PTA) of the renal, tibial, popliteal, femoral and peroneal arteries. These catheters are not for use in coronary arteries. | **Class B** |
| 22 | Bare-metal coronary artery stent | A non-bioabsorbable stent intended to be implanted in a coronary artery or saphenous vein graft of the heart to maintain luminal patency and improve luminal diameter typically in a patient with symptomatic atherosclerotic heart disease. | **Class D** |
| 23 | Bifurcation stent | Intended for improving the side branch luminal diameter of arterial bifurcation liaisons. | **Class D** |
| 24 | Biventricular pacemaker | An MR conditional pulse generator, intended to be implanted in the chest and used with pacing leads placed in the and around the heart to stimulate the heart to beat at a faster rate when it senses bradycardia and provides cardiac resynchronization therapy (CRT) through biventricular electrical stimulation to synchronize right and left ventricular contractions to treat symptoms of heart failure (e.g., easy fatigue) and serious heart-rhythm problems [CRT pacemaker (CRT-P)]; it is not intended for defibrillation therapy. | **Class D** |

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| 25 | Biventricular pacemaker/defibrillator | An MR conditional, implantable device intended to provide cardiac resynchronization therapy (CRT) through biventricular electrical stimulation to synchronize right and left ventricular contractions for more effective blood pumping to treat symptoms of heart failure (e.g., shortness of breath, easy fatigue) and serious heart-rhythm problems [CRT defibrillator (CRT-D)]. It enables conventional pacing and defibrillation functions also. | **Class D** |
| 26 | Cardiac ablation laser system beam guide-catheter | A steerable catheter intended to be used as part of a cardiac ablation laser system to invasively direct and deliver laser energy to the endocardium of a beating heart for the ablation of specific areas in the treatment of cardiac arrhythmias. It is intended to be introduced into the heart via venous access (e.g., femoral vein). | **Class D** |
| 27 | Cardiac ablation solid-state laser system | A device assembly in which input energy (e.g., flashlamp, diode laser) is used to excite a doped glass/crystal medium to emit a high-power laser beam intended for endocardial ablation procedures for the treatment of atrial fibrillation. A laser beam guide catheter and angioscope may be included | **Class D** |
| 28 | Cardiac ablation system applicator introducer/sizer | It is a flexible device intended to determine the appropriate size of a cardiac tissue ablation system applicator [to determine the appropriate number of transducers (ablation cells) required to treat the target tissue] and/or used to introduce and guide it into position, or used to help fix the applicator in position. | **Class C** |
| 29 | Cardiac ablation system irrigation tubing set | A set consisting of sterile flexible tubing and associated items that may include clamps, filters, and connectors, intended to deliver irrigation and/or cooling solution (saline) to an ablation device (e.g., an ablation catheter or a cardiac tissue ablation system applicator) at a specified flow rate during a cardiac electrophysiology (EP) ablation procedure. | **Class B** |
| 30 | Cardiac ablation thoracic motion sensor | A small electronic device intended to be placed on a patient's chest during a cardiac ablation procedure to sense diaphragmatic movement as a means to assess potential phrenic nerve damage. | **Class B** |

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| 31 | Cardiac arrest hypothermia kit | A collection of devices intended to lower the core body temperature of a patient in the short term following a cardiac arrest event to induce and sustain mild hypothermia for improvement of neurological and cognitive prognoses. It typically includes blankets, caps, axilla pads and groin pads, which are filled with a thermally-retentive material (e.g., non-toxic polymer gel) that can be cooled in a freezer. | **Class B** |
| 32 | Cardiac catheterization kit | Cardiac catheterization is a general term for a group of procedures that are performed using this method, such as coronary angiography and left ventricle angiography. | **Class C** |
| 33 | Cardiac catheterization laboratory computer | A dedicated computer intended to calculate, store, and analyse haemodynamic parameters, and other cardiac-related measurements, based on data from catheterization laboratory monitoring/recording. Such data can be pressure measurements that are converted into useful parameters, e.g., cardiac output, pressure gradients, valve areas, shunt flows, vascular resistance, diastolic filling period or systolic ejection period. | **Class C** |
| 34 | Cardiac catheterization monitoring system | An assembly of devices intended to continuously obtain, amplify, and record various signals generated during procedures usually performed in the cardiac catheterization laboratory. The system is intended to be used for procedures such as left heart catheterization, right heart catheterization ventriculograms, coronary angiography, and pacemaker insertions; also used in procedures intended for the determination of most haemodynamic characteristics, evaluation of therapies, and planning of surgical approaches. | **Class D** |
| 35 | Cardiac cryosurgical system | A mobile assembly of mains electricity (AC-powered) devices intended to cryogenically ablate areas of the endocardium of a beating heart in the treatment of cardiac arrhythmias. | **Class D** |
| 36 | Cardiac cryosurgical system catheter (Cardiac cryoablation balloon catheter) | It is intended to be used as part of a cardiac tissue cryosurgical system to cryogenically ablate areas of the endocardium of a beating heart in the treatment of cardiac arrhythmias. | **Class D** |

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| 37 | Cardiac cryosurgical system remote control | A hand-operated electronic unit intended to control the operational functions of a cardiac cryosurgical system and its components (e.g., cardiac tissue ablation catheter) from a distance via a connected cable or wirelessly, during a surgical intervention. | **Class C** |
| 38 | Cardiac defect occluder | An implantable device intended to be used for the minimally-invasive closure of cardiac defects towards the treatment of cardiac disorders that may include (but not limited to) atrial septal defect (ASD), ventricular septal defect (VSD), patent foramen ovale (PFO), or patent ductus arteriosus (PDA). | **Class D** |
| 39 | Cardiac electroacoustic transducer | A device intended to be used to detect the vibrations created by the heart's beating and which are transmitted through organs and tissue to the body surface. | **Class B** |
| 40 | Cardiac electrophysiology analysis system | An assembly of devices intended to perform several diagnostic tests and therapeutic treatments of the heart in patients with arrhythmic or conduction disorders, including analysis of the atrioventricular conduction system, defibrillator function, and/or the induction/termination of ventricular tachycardia. | **Class C** |
| 41 | Cardiac electrophysiology stimulation system | An assembly of devices intended to deliver precisely timed electrical impulses to the heart, during spontaneous and paced rhythms, for diagnostic cardiac stimulation. It is intended to be used for performing physiologic cardiac tests such as to determine the function of various components of the atrioventricular conduction, factors required for induction and termination of tachycardia, and/or to assess sinus node function. | **Class C** |
| 42 | Cardiac electrophysiology workstation | It is a component of a cardiac electrophysiology analysis system consisting of monitor(s), printer(s) and/or graphic recorder(s), data recorder (e.g., optical or magnetic disk), and plug-in modules for signal amplification and/or conditioning. | **Class B** |
| 43 | Cardiac insulation pad | It is intended to be placed around the heart in conjunction with cold cardioplegia during cardiac surgery with extracorporeal circulation. The device is intended to help to prevent rapid rewarming of the heart. | **Class B** |

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| 44 | Cardiac irreversible electroporation system catheter | It is intended to be used as part of a cardiac irreversible electroporation system to apply a series of microsecond electrical pulses to ablate endocardial tissues through irreversible electroporation, to treat cardiac arrhythmia. It is typically also intended to transmit electrical pacing stimuli to, and electrical responses from, the heart for electrophysiological (EP) mapping. | **Class D** |
| 45 | Cardiac irreversible electroporation system generator | A cardiac-dedicated device intended to generate microsecond electrical pulses to produce irreversible cell membrane electroporation and subsequent cell death for the selective nonthermal ablation of cardiac tissues. | **Class D** |
| 46 | Cardiac mapping catheter, percutaneous, single-use | A steerable device intended to transmit electrical impulses to the heart for electrophysiological diagnostic examinations, e.g., intracardiac sensing, endocardial recording, stimulation, temporary pacing for evaluation of cardiac arrhythmias, cardioversion (CV) of electrical arrhythmias or electrophysiology (EP) mapping of cardiac structures. | **Class D** |
| 47 | Cardiac mapping system | An assembly of devices intended to measure, process, and store electronic data for the interpretation of cardiac physiological parameters received from the output of connected measuring devices (e.g., body surface or intracardiac electrocardiograph (ECG) sensors, transducers, and catheters). | **Class C** |
| 48 | Cardiac mapping system application software | An individual software program or group of programs, routines and/or algorithms intended to add specific image processing and/or analysis capabilities to a cardiac mapping system computer for storing, processing and management of electronic information/data used to interpret cardiac physiology parameters. It is a basic set of application programs and routines used for cardiac mapping computer-controlled imaging which can be upgraded to correct programming errors or to add new system capabilities. | **Class C** |
| 49 | Cardiac mapping system electrode array | A component of a cardiac mapping system intended to be worn on the torso to transmit cardiac bioelectric signals to the system for storage, analysis and display of cardiac electrophysiological data. | **Class B** |

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| 50 | Cardiac mapping system reference patch | A component of a cardiac mapping system that is an adhesive device intended to be placed on the surface of a patient's body to provide a fixed reference point for the tip of an internal, non-fluoroscopic catheter during an electrophysiological and electromechanical real-time mapping of the heart. It may also be intended to compensate for patient movement during the procedure. | **Class A** |
| 51 | Cardiac mapping system workstation | A mains electricity (AC-powered) device intended as a control unit to percutaneously navigate (orientate and steer) a cardiac mapping system catheter, or its associated guidewire, in the desired direction to the designated target site (e.g., coronary vasculature). | **Class C** |
| 52 | Cardiac mapping/endocardial-injection catheter | A steerable device intended to be introduced percutaneously into the heart chambers to relay information to an external cardiac mapping system to create a three-dimensional (3-D) electromechanical reconstruction map of the heart chamber. The device may also incorporate a small hollow needle intended for targeted delivery of diagnostic and therapeutic agents into the myocardium. | **Class D** |
| 53 | Cardiac monitor (including cardiotachometer and rate alarm) | A cardiac monitor (including cardiotachometer and rate alarm) is a device used to measure the heart rate from an analog signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor. This device may sound an alarm when the heart rate falls outside preset upper and lower limits. | **Class B** |
| 54 | Cardiac occluder delivery kit | A collection of devices intended to implant a cardiac occluder (not included) for the non-surgical closure of cardiac defects. The kit may include a delivery catheter/sheath, dilator, loading device, delivery cable, and additional items for the intravascular delivery and deployment of a cardiac occluder. | **Class D** |
| 55 | Cardiac occluder/interatrial shunt transcatheter introducer | An implantable intended to be used for the minimally-invasive closure of cardiac defects and deployed using a dedicated delivery catheter/sheath. | **Class D** |

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| 56 | Cardiac pulse generator programmer | An external device intended to enable a healthcare professional in a clinical setting to noninvasively change the settings of, and extract data from, an implanted cardiac pulse generator (e.g., pacemaker, pacemaker/defibrillator). It may be intended to operate independently or in conjunction with a personal computer (PC)/tablet using dedicated software. | **Class C** |
| 57 | Cardiac pulse generator reader, home-use | An external device intended to enable a layperson to noninvasively extract data from an implanted cardiac pulse generator (i.e., therapeutic active cardiac implant) to provide historic and/or current information on device performance, and may in addition be intended to communicate with a diagnostic cardiac implant (e.g., implantable cardiac monitor); it is not intended to program therapeutic implants and is dedicated to cardiac use. | **Class D** |
| 58 | Cardiac pulse generator reader, professional | An external device intended to enable a healthcare professional in a clinical setting to noninvasively extract data from an implanted cardiac pulse generator (i.e., therapeutic active cardiac implant) to obtain historic and/or current information on device performance, and may in addition be intended to communicate with a diagnostic cardiac implant (e.g., implantable cardiac monitor); it is not intended to program therapeutic implants and is dedicated to cardiac use. | **Class C** |
| 59 | Cardiac pulse generator software | An application or operating data program (i.e., primarily operating system software that may include some application program functionality) intended for use in or with an implantable cardioverter-defibrillator (ICD) and an implantable cardiac pacemaker so that the defibrillator and pacemaker function according to their intended purpose. | **Class D** |
| 60 | Cardiac pulse generator test magnet | A magnetized device intended to be used to test an inhibited or triggered type of pacemaker or defibrillator, and cause an inhibited or triggered generator to revert to asynchronous operation. It may also be intended to change the function of the implanted device (e.g., switching to preprogrammed mode or a non-detection mode where external power source may interfere with pacemaker/defibrillator function, etc.). | **Class C** |

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| 61 | Cardiac radio-frequency ablation system catheter | A steerable catheter intended to be used as part of a radio-frequency cardiac ablation system to apply radio-frequency alternating current to ablate areas of the endocardium of a beating heart in the treatment of cardiac arrhythmias; it is typically also intended to transmit electrical pacing stimuli to, and electrical responses from, the heart for electrophysiological (EP) mapping. It may contain monopolar and/or bipolar ablation electrodes. | **Class D** |
| 62 | Cardiac radio-frequency ablation system generator | It is intended to be used to generate radio-frequency energy to create ablative lesions in the cardiac tissue of a beating heart in the treatment of cardiac arrhythmias. It may be intended to be used with a radio-frequency catheter for endocardial ablation and/or an epicardial probe for epicardial ablation. | **Class C** |
| 63 | Cardiac resuscitator chest pad | An electrically conductive device intended to be applied to the chest of a patient to provide a landing surface for a manual cardiac resuscitator during treatment of cardiac arrest [cardiopulmonary resuscitation (CPR)]. The device is intended to be used on adult patients only. | **Class B** |
| 64 | Cardiac resuscitator, battery-powered/line-powered | An external device intended to be used as an adjunct to or substitute of manual external cardiac compressions for the application of rhythmic compression to the chest in the region of the heart to provide blood flow during treatment of cardiac arrest [cardiopulmonary resuscitation (CPR)]. | **Class C** |
| 65 | Cardiac resuscitator, manual | A manually-operated external device (a hand-powered pump) intended to be applied to the chest of a patient suffering cardiac arrest so that a healthcare professional or layperson can administer rhythmic compression to the chest in the region of the heart to provide blood flow during cardiopulmonary resuscitation (CPR). | **Class B** |
| 66 | Cardiac resynchronization therapy implantable defibrillator | An implantable device intended to provide cardiac resynchronization therapy (CRT) through biventricular electrical stimulation to synchronize right and left ventricular contractions for more effective blood pumping to treat symptoms of heart failure (e.g., shortness of breath, easy fatigue) and serious heart-rhythm problems [CRT defibrillator (CRT-D)]. | **Class D** |

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| 67 | Cardiac resynchronization therapy implantable pacemaker | A hermetically-sealed pulse generator, intended to stimulate the heart to beat at a faster rate when it senses bradycardia and provides cardiac resynchronization therapy (CRT) through biventricular electrical stimulation to synchronize right and left ventricular contractions to treat symptoms of heart failure (e.g., easy fatigue) and serious heart-rhythm problems [CRT pacemaker (CRT-P)]; it is not intended for defibrillation therapy. | **Class D** |
| 68 | Cardiac septostomy catheter, balloon | It is intended to create or enlarge the atrial septal defect found in the hearts of infants with congenital cardiac malformations. | **Class D** |
| 69 | Cardiac sizing catheter/balloon | It is intended for use in a patient with a cardiovascular defect wherein accurate measurement of the defect is important to select the appropriately sized occlusion device. | **Class D** |
| 70 | Cardiac stress exercise table | Intended for measurements during cardiac stress exercise. | **Class A** |
| 71 | Cardiac thermodilution catheter | A catheter used in thermodilution for introduction of the cold liquid indicator into the cardiovascular system or for the assessment of a patient's hemodynamic condition through simultaneous right atrial, right ventricular, and pulmonary artery or wedge pressure monitoring, cardiac output determination, and for infusing solutions. | **Class C** |
| 72 | Cardiac transseptal access electrosurgical dilator/needle | It is an electrosurgical device intended to be used with a transseptal vascular guide-catheter (not included) to penetrate the interatrial septum for left-heart access during a transseptal catheterization procedure. | **Class D** |
| 73 | Cardiac transseptal access set | A collection of nonimplantable devices intended to be used to puncture the interatrial septum during a transseptal catheterization procedure, and to create a conduit for the introduction of various cardiovascular catheters into the left side of the heart. It includes a vascular guide-catheter (referred to as a steerable introducer) with a transseptal needle to create the puncture, and may also include additional introduction assistive devices necessary for the procedure (e.g., stylet, guidewire, dilator). | **Class D** |
| 74 | Cardiac transseptal needle, single-use | A device intended to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access typically to facilitate fluid aspiration and | **Class D** |

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| | | injection/infusion, blood sampling, and pressure monitoring. | |
| 75 | Cardiac valvuloplasty catheter | A device intended to perform plastic or restorative surgery on a cardiac valve, i.e., for the dilatation of atrioventricular, aortic, and pulmonary trunk valves. | **Class D** |
| 76 | Cardiac ventriculography catheter | A device intended to enter the left or right ventricle to perform diagnostic haemodynamic/angiographic procedures with contrast media. | **Class D** |
| 77 | Cardiac/peripheral vascular guidewire, single-use | A device intended to be percutaneously placed into the cardiac vasculature (ventricles or coronary vessels) to function as a guide for the introduction, positioning, and/or operation of a device (e.g., catheter, pacing lead); it may also be used in the peripheral vasculature. It may include devices used to facilitate manipulation (e.g., torque device). | **Class D** |
| 78 | Cardiokymograph | An electrocardiograph that records heart wall motion (mainly motion of the left ventricular anterior wall) on an amplitude vs. time graph (heart kymograph). | **Class B** |
| 79 | Cardioplegia cannula | A device intended to deliver cardioplegic solution to the aortic root to stop the beating of the heart and maintain it dormant; it may also be used to vent the aorta and the left heart during a cardiopulmonary bypass procedure. | **Class C** |
| 80 | Cardioplegia solution administration adaptor | A device intended to facilitate/regulate the delivery of cardioplegic solution to the heart during a cardiopulmonary bypass procedure by connecting an administration line to a cardioplegia cannula. | **Class B** |
| 81 | Cardioplegia solution administration kit | A collection of devices intended to be used to infuse cardioplegia solution into the heart to interrupt its contractions during cardiopulmonary bypass surgery. It typically consists of tubing/adaptor, a filter, and a heat exchanger. | **Class B** |

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| 82 | Cardiopulmonary bypass arterial line blood filter | A cardiopulmonary bypass arterial line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (blood clots or pieces of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. It is used in the arterial return line. | **Class B** |
| 83 | Cardiopulmonary bypass bubble detector | A cardiopulmonary bypass bubble detector is a device used to detect bubbles in the arterial return line of the cardiopulmonary bypass circuit. | **Class B** |
| 84 | Cardiopulmonary bypass cannula holder set | A collection of devices intended to help secure a cardiopulmonary bypass cannula to the underlying tissue in the operative field to minimize displacement of the cannula during cardiopulmonary bypass surgery. | **Class B** |
| 85 | Cardiopulmonary bypass cannula, femoral | A device intended to be inserted into a femoral artery or vein during cardiopulmonary bypass procedures. The tube is used in set-ups/systems intended to divert the patient's blood to and from external tubing and an arterial pump, bypassing the heart and lungs completely. | **Class D** |
| 86 | Cardiopulmonary bypass cardiotomy suction line blood filter | A cardiopulmonary bypass cardiotomy suction line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (a blood clot or a piece of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. This device is intended for use in the cardiotomy suction line. | **Class C** |
| 87 | Cardiopulmonary bypass defoamer | A cardiopulmonary bypass defoamer is a device used in conjunction with an oxygenator during cardiopulmonary bypass surgery to remove gas bubbles from the blood. | **Class C** |
| 88 | Cardiopulmonary bypass heart-lung machine console | A cardiopulmonary bypass heart- lung machine console is a device that consists of a control panel and the electrical power and control circuitry for a heart-lung machine. The console is designed to interface with the basic units used in a gas exchange system, including the pumps, oxygenator, and heat exchanger. | **Class B** |

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| 89 | Cardiopulmonary bypass pulsatile flow generator | A cardiopulmonary bypass pulsatile flow generator is an electrically and pneumatically operated device used to create pulsatile blood flow. The device is placed in a cardiopulmonary bypass circuit downstream from the oxygenator. | **Class B** |
| 90 | Cardiopulmonary bypass system blood gas monitor, in-line | An assembly of devices intended to monitor venous and arterial blood gas parameters in cardiopulmonary bypass procedures. It may be intended for adult and/or pediatric population. | **Class C** |
| 91 | Cardiopulmonary bypass system blood gas sensor | A transducer intended to be used with a cardiopulmonary bypass system to detect and measure the partial pressure of gases in the blood being circulated by the system. | **Class C** |
| 92 | Cardiopulmonary bypass system blood tubing set | A collection of devices consisting of tubing and typically clamps, filters, connectors, and stopcocks, used in a circuit for a cardiopulmonary bypass procedure. | **Class C** |
| 93 | Cardiopulmonary bypass system centrifugal pump | A device intended to be connected to a drive unit (not included) to circulate blood through the extracorporeal circuit of a non-roller type cardiopulmonary bypass system, via a centrifugal force mechanism, for gas exchange and reinfusion; it may in addition be used in extracorporeal support systems for ventricular support/circulatory assistance. | **Class C** |
| 94 | Cardiopulmonary bypass system centrifugal pump drive unit | A device that powers and controls the speed of a disposable cardiovascular bypass system centrifugal pump, to which it is connected, for the circulation of blood through the extracorporeal circuit for gas exchange and reinfusion. This device drives the centrifugal rotor of the disposable centrifugal pump using magnetism. | **Class B** |
| 95 | Cardiopulmonary bypass system filter, priming solution | A porous, sterile device intended to be used to filter the nonhaemic priming solution used in the heart-lung bypass extracorporeal circuit to remove particulates or other debris from the circuit prior to the initiation of the cardiopulmonary bypass surgery procedure. | **Class B** |
| 96 | Cardiopulmonary bypass system filter, venous blood line (Blood transfusion filter) | A microporous device intended to remove gross air in the venous line before it is entering the arterial pump and the components of the extracorporeal circuit (ECC). | **Class C** |

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| 97 | Cardiopulmonary bypass system gas control unit | A device that is a module of a cardiopulmonary bypass system and that is intended to control and measure the flow of gas supplied into the oxygenator. | **Class C** |
| 98 | Cardiopulmonary bypass system heat exchanger, reusable/single use | A device consisting of a heat exchanging system intended to be used in extracorporeal circulation to warm or cool the blood or perfusion fluid flowing through the device for the purposes of cardiopulmonary bypass intervention or treatment. | **Class C** |
| 99 | Cardiopulmonary bypass system heat exchanger, single-use | A device consisting of a heat exchanging system intended to be used in extracorporeal circulation to warm or cool the blood or perfusion fluid flowing through the device for the purposes of cardiopulmonary bypass intervention or treatment. | **Class C** |
| 100 | Cardiopulmonary bypass system heating/cooling unit | A mains electricity (AC-powered) component of a cardiopulmonary bypass system intended to heat or cool a patient's body by extracorporeal heat exchange with the patient's perfused blood during a cardiopulmonary bypass procedure. | **Class C** |
| 101 | Cardiopulmonary bypass system mounting unit (heart-lung bypass system module, console) | A platform upon which modular devices of a cardiopulmonary bypass system (e.g., the blood pumps) are mounted to form the complete system. It serves as the basic workstation for the operator to monitor and control the system's functions. | **Class C** |
| 102 | Cardiopulmonary bypass system priming set | It is intended to be used in open heart surgery to facilitate the transfer of priming fluids during the priming of the extracorporeal circuit of a cardiopulmonary bypass system. | **Class B** |
| 103 | Cardiopulmonary bypass system roller pump | A mains electricity (AC-powered) device that is a module of a cardiopulmonary bypass system and is intended to circulate the blood flow outside of the body for gas exchange and reinfusion via a roller type mechanism. This pump can also be used to deliver cardioplegia solution at a controlled volume to the patient. | **Class C** |
| 104 | Cardiopulmonary bypass system valve, unidirectional flow/pressure control | A mechanical regulator intended to be used in a cardiopulmonary bypass system, particularly systems employing centrifugal pumps during open-heart surgeryto provide unidirectional flow, preventing inadvertent backflow of blood and air into the heart, and/or control the pressure within the system. | **Class B** |

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| 105 | Cardiopulmonary bypass temperature controller | A cardiopulmonary bypass temperature controller is a device used to control the temperature of the fluid entering and leaving a heat exchanger. | **Class B** |
| 106 | Cardiopulmonary bypass vascular catheter, cannula, or tubing | A cardiopulmonary bypass vascular catheter, cannula, or tubing is a device used in cardiopulmonary surgery to cannulate the vessels, perfuse the coronary arteries, and to interconnect the catheters and cannulas with an oxygenator. The device includes accessory bypass equipment. | **Class B** |
| 107 | Cardiopulmonary bypass/extracorporeal membrane oxygen (ECMO) drainage cannula (Venous cannula) | A semi-rigid or rigid tube intended to be surgically inserted into the right atrium or large vein to serve as a channel for the extracorporeal transport of deoxygenated blood from a patient during cardiopulmonary bypass and/or extracorporeal membrane oxygenation; in some settings it may be referred to as a venous cannula. | **Class D** |
| 108 | Cardiopulmonary bypass/extracorporeal membrane oxygen (ECMO) return cannula (Arterial cannula) | A semi-rigid or rigid tube intended to be surgically inserted into an artery or vein to serve as a channel for the extracorporeal transport of oxygenated blood to a patient during cardiopulmonary bypass and/or extracorporeal membrane oxygenation. | **Class D** |
| 109 | Cardiopulmonary parameter spot-check measurement software | An application software program intended to be installed on a computer/workstation to assist a healthcare provider in the spot-check (user-initiated) measurement of a cardiovascular and/or pulmonary parameter(s) [e.g., blood pressure, electrocardiography (ECG), respiratory rate, haemoglobin oxygen saturation (SpO2)]; it might also be intended for additional physiological measurements [e.g., electromyography (EMG), galvanic skin response (GSR)]. It is intended to display, store, and allow communication of the physiological data, and may include interpretive algorithms to assist diagnosis; it is not intended for continuous bedside/intraoperative monitoring. | **Class B** |

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| 110 | Cardiopulmonary physiological parameter analysis software | A software program intended to add image processing and/or data analysis capabilities to a computer/workstation for the interpretation and/or screening of cardiopulmonary physiological parameters [e.g., electrocardiogram (ECG), blood pressure, vital capacity (VC)]. It is intended for use exclusively by healthcare professionals and may provide risk assessment for cardiopulmonary events [e.g., acute myocardial infarction (AMI)] or screen for specific conditions (e.g., low ejection fraction). It might include machine learning (ML) technology. | **Class C** |
| 111 | Cardiopulmonary resuscitation feedback device | A manually-operated device intended to be applied to the chest of a patient experiencing cardiac arrest to assist a person trained in cardiopulmonary resuscitation (CPR) to deliver effective manual chest compressions. It is intended to translate an applied downward force into a chest compression and may also assist the timing of chest compressions. | **Class B** |
| 112 | Cardiopulmonary stress exercise monitoring system | An assembly of devices intended to noninvasively assess the cardiopulmonary response to exercise or measure of energy expenditure using indirect calorimetry. The system typically monitors functions such as continuous electrocardiogram (ECG), O2 and CO2 levels, etc. | **Class B** |
| 113 | Cardiopulmonary stress exercise monitoring system computer | A dedicated computer with a specific software package installed and intended to interpret the various physiological parameters and waveforms generated during stress exercise testing of a patient while connected to a stress exercise monitoring system. | **Class B** |
| 114 | Cardiothoracic implant introduction kit | A collection of devices intended to assist the surgical introduction of an implantable cardiothoracic device (e.g., implantable cardiac monitor) within a subcutaneous cavity in the thorax; it is not intended for implantation within an organ (i.e., heart, lungs or blood vessels). | **Class C** |
| 115 | Cardiotocography telemetric monitoring system | An assembly of devices intended to be used to continuously measure and wirelessly transmit foetal heart rate and uterine contraction signals from a patient to a cardiotocograph/monitor. | **Class C** |

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| 116 | Cardiotocography telemetric monitoring system receiver | A component of a cardiotocography telemetric monitoring system intended to receive wireless signals from the transmitter that senses fetal heart rate and uterine contractions during labor. | **Class B** |
| 117 | Cardiotocography telemetric monitoring system transmitter | A component of a cardiotocography telemetric monitoring system intended to continuously measure and wirelessly transmit foetal heart rate and uterine contraction signals to the system's receiver. | **Class B** |
| 118 | Cardiotomy reservoir | A device intended to be integrated within an extracorporeal circuit to collect, store, and filter blood typically during a cardiopulmonary bypass procedure; it does not include additional functional components such as an oxygenator. | **Class C** |
| 119 | Cardiovascular catheter | A thin, hollow tube called a catheter is inserted into a large blood vessel that leads to heart. | **Class D** |
| 120 | Cardiovascular catheter sheath | A device intended to be used during cardiovascular catheterization (e.g., femoral, pulmonary) to cover and protect the exposed proximal end of a cardiovascular catheter to prevent contamination (extending the sterile field of the external catheter) and/or to contain a backflow of blood (e.g., during catheter introduction, repositioning or removal). | **Classs B** |
| 121 | Cardiovascular embolization implantation kit | A collection of dedicated instruments intended to be used for the implantation of an embolization implant (implant not included). (e.g., needle, introducer, guidewires, catheter). | **Class D** |
| 122 | Cardiovascular implant implantation tool base | A sterile plate-like device intended to function as a sturdy support (base) for the holder/implantation tool of a cardiovascular implant (e.g., biologic-polymer aorta graft, heart valve bioprosthesis). | **Class A** |
| 123 | Cardiovascular patch, animal-derived | An implantable material intended to reinforce suture lines and/or increase the strength of weak or injured cardiac and/or peripheral vascular tissues during cardiovascular repair/reconstruction procedures (e.g., annulus or septal defect repair, endarterectomy, profundaplasty). | **Class D** |

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| 124 | Cardiovascular patch, synthetic | An implantable material intended to reinforce suture lines and/or increase the strength of weak or injured cardiac and/or peripheral vascular tissues during cardiovascular repair/reconstruction procedures (e.g., annulus or septal defect repair, endarterectomy, profundaplasty). | **Class D** |
| 125 | Cardiovascular prosthetic devices | An intra-cardiac patch or pledget which is a medical device placed in the heart and is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures. | **Class D** |
| 126 | Cardiovascular risk/probability assessment interpretive software | An interpretive software program intended to be used in the assessment of risk/probability for having a cardiovascular condition (e.g., significant coronary stenosis) or event (e.g., heart attack, ischemic stroke, unstable angina, coronary revascularization). | **Class B** |
| 127 | Cardiovascular-risk peripheral arterial tonometry system | An assembly of devices intended to assess peripheral artery endothelial dysfunction (poor vasodilatory response) and/or arterial stiffness through the noninvasive measurement of arterial pulsatile volume changes in the fingertip during a reactive hyperemia test (occlusion of blood flow followed by abrupt release). | **Class B** |
| 128 | Cardiovascular-risk peripheral arterial tonometry system sensor | A pneumo-electronic device, usually integrated into a cuff-like device intended to be placed on a patient's finger during a reactive hyperemia test for the assessment of endothelial dysfunction (poor vasodilatory response) and arterial stiffness. | **Class B** |
| 129 | Carotid artery shunt | It is intended to serve as a temporary blood conduit (a shunt) connecting the distal internal carotid artery to the proximal common carotid artery allowing intravascular blood to continuously flow to the patient's brain during an endarterectomy procedure. | **Class D** |
| 130 | Carotid filter system | Intended to be used while performing angioplasty and stenting procedures in carotid arteries. | **Class D** |
| 131 | Carotid sinus nerve stimulator | A carotid sinus nerve stimulator is an implantable device used to decrease arterial pressure by stimulating Hering's nerve at the carotid sinus. | **Class D** |

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| 132 | Catheter guidewire | It is intended to facilitate the placement of balloon dilatation catheters during percutaneous angioplasty (PTCA) and percutaneous transluminal coronary transluminal angioplasty (PTA). The PTCA Guide Wires are not to be used in the cerebral blood vessel. | **Class D** |
| 133 | Central venous catheter | It is indicated for use in patients requiring administration of solutions, blood sampling, central venous pressure monitoring and injection of contrast media. | **Class B** |
| 134 | Central venous catheter inside-out introduction set | A collection of invasive devices intended to enable introduction of a central venous catheter (CVC) into an occluded vein (e.g., subclavian) by creating a puncture site from the inside of the vein under fluoroscopic guidance. | **Class D** |
| 135 | Central venous catheter navigation system, electrocardiographic | An assembly of devices intended to use electrocardiographic (ECG) data to assist guidance and positioning of a central venous catheter [e.g., peripherally-inserted central catheter (PICC), central venous catheter (CVC), haemodialysis catheter]. | **Class C** |
| 136 | Central venous catheter navigation system, electrocardiographic/magnetic | An assembly of devices intended to use electrocardiographic (ECG) and magnetic data to assist guidance and positioning of a central venous catheter [e.g., peripherally-inserted central catheter (PICC)]. | **Class C** |
| 137 | Central venous catheterization kit, long-term | A collection of devices and materials intended for the long-term (>30 days) introduction of a central venous catheter (CVC) for various infusion/aspiration procedures (i.e., non-dedicated). | **Class D** |
| 138 | Central venous catheterization kit, short-term | A collection of devices and materials intended for the short-term (<= 30 days) introduction of a central venous catheter (CVC) for various infusion/aspiration procedures (i.e., non-dedicated). | **Class D** |
| 139 | Central/peripheral venous pressure monitor | A device that measures and records invasive central or peripheral venous blood pressure measurements, or the difference between the central and peripheral venous pressures of the patient using an indwelling catheter and a pressure manometer. | **Class C** |

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| 140 | Centrally-inserted central venous catheter | It is intended to be introduced into a neck or thoracic vein and often advanced into the superior vena cava for various infusion/aspiration procedures (i.e., non-dedicated) including the intravenous administration of nutrients, fluids, chemotherapeutic agents or other drugs, and blood sampling or delivery; it may also be used to monitor venous pressure. | **Class D** |
| 141 | Chamber-decompression cardiac catheter (Cardiac vent catheter) | It is intended to decompress a heart chamber, especially left ventricle, by removing blood, air and/or other debris during a surgical procedure such as a cardiopulmonary bypass. It may include a pressure monitoring line to continuously measure the pressure of a chamber. | **Class D** |
| 143 | Cholangiography catheter | Diagnostic evaluation of the bile ducts during laparoscopic cholecystectomy procedures. | **Class B** |
| 144 | Cholangiography needle | It is intended to be used to deliver contrast media to the biliary tract for cholangiographic procedures. This is a single-use device. | **Class B** |
| 145 | Coronary angioplasty balloon catheter, basic | It is intended for percutaneous transluminal coronary angioplasty (PTCA) to dilate a stenotic coronary artery by controlled inflation of a distensible balloon(s) at its distal tip. | **Class D** |
| 146 | Coronary angioplasty balloon catheter, cutting/scoring | It is intended for use in percutaneous transluminal coronary angioplasty (PTCA) to dilate a stenotic coronary artery and increase myocardial perfusion by controlled inflation of a distensible balloon with peripheral cutting/scoring elements (e.g., microsurgical atherotomes) intended to remove stenotic material. | **Class D** |
| 147 | Coronary angioplasty balloon catheter, drug-coated | It is intended for percutaneous transluminal coronary angioplasty (PTCA) to dilate an atherosclerotic stenotic coronary artery by controlled inflation of a distal distensible balloon, and to simultaneously release a drug intended to inhibit restenosis. | **Class D** |
| 148 | Coronary angioplasty balloon catheter, perfusing | It is intended for use in percutaneous transluminal coronary angioplasty (PTCA) to dilate a stenotic coronary artery by controlled inflation of a distensible balloon. | **Class D** |

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| 149 | Coronary artery clamp | A manual surgical instrument intended to directly compress a coronary artery during coronary artery graft surgery to create a temporary atraumatic haemostasis (arrest or prevention of bleeding). | **Class B** |
| 150 | Coronary artery exposure retractor | A surgical instrument intended to be used during cardiac bypass graft anastomosis surgery to provide hands-free (self-retaining) retraction of the fatty surface layer over the myocardium adjacent to the coronary artery, to facilitate exposure of the artery. | **Class B** |
| 151 | Coronary artery guidewire extension | It is intended to provide the necessary length to allow the exchange of one coronary artery dilatation catheter for another, while maintaining the position of the cardiac catheter guidewire in the coronary artery, during angiography or percutaneous transluminal coronary angioplasty (PTCA). | **Class A** |
| 152 | Coronary artery infusion catheter | It is intended to access the coronary artery vasculature for local infusion of diagnostic or therapeutic solutions (e.g., angiographic contrast medium, heparin solution, saline), and often to function as a passage for a guidewire to assist its placement in the coronary artery. | **Class D** |
| 153 | Coronary artery occluder | A device used to temporarily ligate and fix the coronary artery using a snare during the off-pump coronary artery bypass grafting (CABG). | **Class D** |
| 154 | Coronary artery perfusion catheter | It is intended to perfuse the coronary arteries with shunted blood (e.g., from a femoral artery) to prevent ischemia typically during off-pump coronary artery bypass grafting or during minimally-invasive cardiac surgical procedures. | **Class D** |
| 155 | Coronary dilatation catheter | It is intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. | **Class D** |
| 156 | Coronary sinus cannula | It is intended to be surgically inserted, temporarily, into the ostium of the coronary sinus to provide retrograde coronary perfusion/cardioplegia during cardiopulmonary bypass or minimally invasive surgery. | **Class D** |
| 157 | Coronary sinus venogram catheter | It is intended for use within the coronary sinus to infuse contrast medium solution into the coronary vasculature for venogram imaging procedures. | **Class D** |

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| 158 | Coronary venous pacing lead | It is a flexible device intended to serve as an electrical conductor to transmit pacing impulses from an implanted cardiac resynchronization therapy (CRT) pulse generator to the left ventricle of the heart. | **Class D** |
| 159 | Coronary venous pacing lead | An MR conditional implantable device intended to serve as an electrical conductor to transmit pacing impulses from an implanted cardiac resynchronization therapy (CRT) pulse generator to the left ventricle of the heart. It may also transmit electrical responses from the heart back to the pacemaker; it is not intended to conduct defibrillation impulses. | **Class D** |
| 160 | Counterpressure sphygmomanometer | An automatic electronic sphygmomanometer intended to noninvasively measure blood pressure using a self-contained software program that regulates automatic finger-cuff inflation and measurement cycles. that measures the change in blood volume taking place in a single finger. | **Class B** |
| 161 | Doppler blood-flow measurement ultrasound system | A portable or stationary ultrasonic device that does not produce 2-dimensional or 3-dimensional images, and is intended to be used for determining various blood-flow related parameters of the heart, artery, or vein. | **Class C** |
| 162 | Drug-coated-metal coronary artery stent | A non-bioabsorbable device coated with a drug, intended to be implanted via a delivery catheter into a coronary artery (or saphenous vein graft) to maintain its patency. | **Class D** |
| 163 | Drug-eluting coronary artery stent, antibody-coated | It is intended to be implanted via a delivery catheter into a coronary artery (or saphenous vein graft) to maintain its patency. | **Class D** |
| 164 | Drug-eluting coronary artery stent, bioabsorbable-polymer-coated | A non-bioabsorbable device covered with a bioabsorbable polymer that contains a drug, intended to be implanted via a delivery catheter into a coronary artery (or saphenous vein graft) to maintain its patency typically in a patient with symptomatic atherosclerotic heart disease. | **Class D** |
| 165 | Drug-eluting coronary artery stent, fully-bioabsorbable | A bioabsorbable device with a drug coating intended to be implanted, via a delivery catheter, into a de novo or restenotic native coronary artery during a percutaneous coronary intervention (PCI) to temporarily maintain its patency, typically in patients with symptomatic atherosclerotic heart disease. | **Class D** |

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| 166 | Drug-eluting coronary artery stent, non-bioabsorbable-polymer-coated | A non-bioabsorbable device covered with a non-bioabsorbable polymer and a drug coating, that is intended to be implanted, via a delivery catheter, into a coronary artery (or saphenous vein graft) to maintain its patency typically in a patient with symptomatic atherosclerotic heart disease. | **Class D** |
| 167 | Dual-chamber automatic implantable defibrillator | An implantable pulse generator with a cardiac rhythm recognition system intended to collect and analyse electrocardiogram (ECG) data and deliver appropriate electrical impulses to defibrillate the heart (restore normal rhythm) or slow a rapid heart rate, and to pace the heart (to treat bradycardia). It is commonly known as an automatic implantable cardioverter-defibrillator (AICD). | **Class D** |
| 168 | Dual-chamber implantable pacemaker, demand | A battery-powered, implantable device consisting of a hermetically-sealed pulse generator with dual chamber pacing leads and intended to generate and conduct electrical impulses to the heart typically when the heart beats too slowly (bradycardia) or has other abnormal rhythms (arrhythmias). It provides a stimulus only when electrical activity within the heart is sensed to be abnormal (demand); it is not intended for defibrillation therapy. | **Class D** |
| 169 | Dual-chamber implantable pacemaker, rate-responsive | It is a battery-powered, implantable pulse generator with dual chamber pacing leads, intended to stimulate the chambers of an abnormal heart, through electrical impulses, to beat in their natural sequence, and to adjust the rate of contraction to meet the body's increased need for blood flow due to activity. | **Class D** |
| 170 | Dual-chamber pacemaker, rate-responsive | It is intended to stimulate the chambers of an abnormal heart, through electrical impulses, to beat in their natural sequence, and to adjust the rate of contraction to meet the body's increased need for blood flow due to activity. It is not intended for defibrillation therapy. It may be MR conditional. | **Class D** |
| 171 | Echocardiograph | An echocardiograph is a device that uses ultrasonic energy to create images of cardiovascular structures. It includes phased arrays and two-dimensional scanners. | **Class B** |

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| 172 | Electrocardiograph, home-use | A device intended to be used by a layperson in the home to acquire and process the electrical activity of the heart for digital display in the form of a graph, to assist a physician in assessing electrical cardiac physiology [electrocardiography (ECG)]. | **Class B** |
| 173 | Electrocardiograph, professional, multichannel | A device intended to be used by a healthcare professional in a clinical setting to acquire and process the electrical activity of the heart for digital display in the form of a graph, to assist a physician in assessing electrical cardiac physiology [electrocardiography (ECG)]. It is designed for recording the electrical signal from two or more configurations of electrodes (ECG-leads) at a time (multichannel) and may be intended for resting ECG and/or stress/exercise ECG. | **Class B** |
| 174 | Electrocardiograph, professional, single-channel | A device intended to be used by a healthcare professional in a clinical setting to acquire and process the electrical activity of the heart for digital display in the form of a graph, to assist a physician in assessing electrical cardiac physiology [electrocardiography (ECG)]. It is designed for recording the electrical signal from only one configuration of electrodes (ECG-leads) at a time (single-channel). | **Class B** |
| 175 | Electrocardiographic ambulatory recorder (Long term/Holter ECG recorder) | It is intended to be worn by a patient during daily activities for 24-hour recording of the electrocardiographic signals of the heart, for the diagnosis of cardiac disorders (e.g., arrhythmias). | **Class B** |
| 176 | Electrocardiographic electrode, reusable/single-use | A noninvasive electrical conductor intended to conduct electrical signals, generated by a patient's heart, from the skin surface to an electrocardiograph (ECG) monitoring device, via an ECG lead wire (not included). | **Class B** |
| 177 | Electrocardiographic lead/catheter adaptor | It is intended to enable a mechanical union between an in situ cardiac catheter [e.g., an electrophysiology (EP) diagnostic catheter] and an electrocardiograph (ECG) cable/lead for transmission of heart signals to an ECG machine, that may otherwise be incompatible. | **Class A** |

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| 178 | Electrocardiographic long-term ambulatory recording analyser | An electronic device intended to be used for the analysis of long-term (often 24-hours) heart activity data, which has previously been registered by an electrocardiographic long-term ambulatory recorder (Holter), to which the patient was connected and carried upon his or her person. | **Class B** |
| 179 | Electrocardiographic monitor | A patient bedside device intended to continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient; it also typically displays heart rate. | **Class B** |
| 180 | Electrocardiographic recording paper | A device prepared from a thin sheet of fibrous material, typically with preprinted graphics and intended for recording the output of an electrocardiograph (ECG), or other device, in the form of measured physiologic parameters as an electrocardiogram (ECG). | **Class A** |
| 181 | Electrocardiographic signal amplifier | An electrical device intended to amplify the signal level and provide impedance matching between two or more medical devices when bioelectrical signals from the heart are transmitted between them. | **Class B** |
| 182 | Electrocardiography monitoring system receiver | A component of an electrocardiograpy telemetric monitoring system intended to wirelessly receive, consolidate, and display electrocardiographic (ECG) signals [sometimes with an additional parameter such as haemoglobin oxygen saturation (SpO2)] from a transmitter connected to a patient, typically ambulatory, for viewing at a receiving location (e.g., central station, bedside monitor). | **Class B** |
| 183 | Electrocardiography telemetric monitoring system | An assembly of devices intended to continuously measure and wirelessly transmit electrocardiographic (ECG) signals from a patient to a receiving location (e.g., central station, bedside monitor) for viewing. | **Class B** |
| 184 | Electrocardiography telemetric monitoring system transmitter | A body-worn component of an electrocardiography telemetric monitoring system intended to continuously measure and wirelessly transmit real-time electrocardiographic (ECG) signals [and sometimes additional parameters such as heart rate, skin temperature, or haemoglobin oxygen saturation (SpO2)] to a remote receiver (e.g., central station server); it may in addition record/analyse data during a period of time for later retrieval (Holter reporting). | **Class B** |

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| 185 | Electrode recording probe, Electrode recording catheter | A cardiac catheter containing one or more electrodes; it may be used to pace the heart or to deliver high energy shocks. | **Class D** |
| 186 | Electromagnetic blood flowmeter | A device that provides confirmation and measurement of the blood flow velocity after coronary artery bypass surgery, organ transplantation and other forms of revascularization. | **Class B** |
| 187 | Electronic sphygmomanometer, home use | An electronic device intended to be used in indirect (noninvasive) measurement of blood pressure. The device is intended for self-measurement of blood pressure at home under a physician's supervision, for the purpose of self-management of blood pressure by the user. | **Class B** |
| 188 | Electrosurgical cardiac ablation electrode/catheter | It is a component of an electrosurgical assembly intended to deliver electrosurgical current in a monopolar configuration (i.e., used with a patient contact return electrode) to tissues for cutting/coagulation/ablation during endoscopic (e.g., laparoscopic, arthroscopic) surgery. | **Class D** |
| 189 | Embolic filter system | It is indicated for general use as a guidewire and embolic protection system during angioplasty and stenting procedures in carotid arteries with reference vessel diameters of 2.5 to 5.5 mm. | **Class B** |
| 190 | Endocardial/interventricular septal pacing lead | It is intended for pacing and sensing in the right atrium or right ventricle. It may also be intended for pacing and sensing at the bundle of His or in the left bundle branch area as an alternative to right ventricular pacing in a single or dual chamber pacing system. It may be MR conditional. | **Class D** |
| 191 | Endomyocardial biopsy device | An endomyocardial biopsy device is a device used in a catheterization procedure to remove samples of tissue from the inner wall of the heart. | **Class D** |

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| 192 | Epicardial pacing lead | This implantable device is intended to transmit pacing impulses from an implanted pacemaker to the heart. It may also transmit electrical responses from the heart back to the pacemaker; it is not intended to conduct defibrillation impulses. The electrode end is normally implanted in the outer surface of the heart (epicardium) in close contact to the wall of one of the chambers of the heart (endocardium). It may also be impregnated with a steroid (e.g., dexamethasone) intended to elute into the tissues to reduce inflammation. | **Class D** |
| 193 | Epicardial pacing lead inserter | A manually-powered, mechanical surgical instrument intended for the implantation of a pacing lead in the epicardium. | **Class C** |
| 194 | External cardiac compressor | An external cardiac compressor is an externally applied prescription device that is electrically, pneumatically, or manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest. External cardiac compressor devices are used as an adjunct to manual cardiopulmonary resuscitation (CPR) when effective manual CPR is not possible (*e.g.,* during patient transport or extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or when insufficient EMS personnel are available to provide effective CPR). | **Class B** |
| 195 | External defibrillator tester | An electronic instrument used to test an external defibrillator to ensure compliance with performance specifications by connecting to the output of the defibrillator and measuring the energy delivered by the defibrillator; it may also perform transcutaneous pacemaker testing, provide waveform information, and execute other quality control procedures. | **Class C** |
| 196 | External pacemaker analyzer | An electronic instrument designed to test an external pacemaker to ensure compliance with performance specifications by testing any or all of the pulse generator's parameters including pulse duration, pulse amplitude, pulse rate, and sensing threshold. | **Class C** |

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| 197 | External pacemaker, epicardial pacing | An external pulse generator (EPG) intended to generate periodic electrical cardiac pacing impulses and transmits them to the heart via invasive (percutaneous) leads to stimulate the heart when the sino-atrial (SA) node is not functioning properly or when the heart has a conductive disorder. It is commonly used: 1) in an emergency; 2) during surgery; or 3) following open-heart surgery until the heart recovers. It is not intended for defibrillation or cardioversion. | **Class D** |
| 198 | External pacemaker, transcutaneous pacing | An external pulse generator (EPG) intended to generate electrical cardiac pacing impulses to stimulate the entire heart simultaneously to resuscitate the patient, restore normal cardiac rhythm, and/or temporarily pace the heart during invasive procedures that may induce cardiac arrhythmias or asystole (cardiac standstill). | **Class C** |
| 199 | External pacemaker, transoesophagal pacing | A device intended to generate electrical cardiac pacing impulses from an external pulse generator (EPG), located outside the body, and transmit them to the heart via its leads that are placed in the oesophagus. The device is used for temporary stimulation of the heart. | **Class C** |
| 200 | Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure | An extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary support (>6 hours) is a system of devices and accessories that provides assisted extracorporeal circulation and physiologic gas exchange of the patient's blood in patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. The main devices and accessories of the system include, but are not limited to, the console (hardware), software, and disposables, including, but not limited to, an oxygenator, blood pump, heat exchanger, cannulae, tubing, filters, and other accessories (*e.g.,* monitors, detectors, sensors, connectors). | **Class C** |
| 201 | Extracorporeal membrane oxygenator | A device designed for the extracorporeal diffusion of oxygen into blood across a gas-permeable membrane during a cardiopulmonary bypass or extracorporeal membrane oxygenation procedure. | **Class C** |

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| 202 | Femoral artery catheter introduction/wound closure set | A collection of invasive devices intended to: 1) provide percutaneous femoral artery access to enable introduction of a catheter (not included) into the vascular system; and 2) plug the femoral artery puncture site following catheterization to provide haemostasis. | **Class D** |
| 203 | Femoral artery closure plug/patch, collagen | An implantable, bioabsorbable device intended for haemostasis/closure of a puncture site, through pressure/compression, on a patient having undergone femoral artery catheterization. | **Class D** |
| 204 | Femoral artery closure plug/patch, synthetic polymer | An implantable, bioabsorbable device intended for haemostasis/closure of a puncture site, through pressure/compression, on a patient having undergone femoral artery catheterization. | **Class D** |
| 205 | Fetal heart phonodetector | A device that detects fetal heart sounds sonically, utilizing ECG with a function to capture heart sounds. | **Class B** |
| 206 | Flow directed catheter | Used for venous sampling and pressure monitoring. | **Class B** |
| 207 | Foetal cardiac monitor | A device intended to detect, measure, and display foetal heart activity during the perinatal period. | **Class C** |
| 208 | Heart donor-organ preservation/transport perfusion set | A collection of devices intended to support and provide continuous physiologic organ perfusion to a donated heart during its preservation, evaluation, and transport in a heart donor-organ preservation/transport system from the donor to the receiver hospital where the organ will be transplanted into the recipient. It typically includes a blood/fluid perfusion circuit, reservoir, pump, oxygenator, warmer, electrocardiograph and defibrillator leads, flow/pressure sensors, access and control valves, cannulae/connectors/tools to connect the appropriate vessels of the heart and tubing lines, filters and bags to add/remove blood and solutions. | **Class C** |
| 209 | Heart donor-organ preservation/transport system (control console included) | This system is intended to support and maintain a donated heart organ during transport from the donor to the receiver hospital where the organ will be transplanted into the recipient. This system will provide technical support functions to keep the organ in as near-physiologic state as possible. | **Class C** |

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| 210 | Heart valve annulus sizer, reusable/single-use | A manual surgical instrument intended to be used during heart valve repair or replacement that enables evaluation of the valve opening (patent annulus) into which the appropriately sized annuloplasty ring or replacement valve will be implanted. | **Class B** |
| 211 | Heart valve clip | An implantable device intended for the reconstruction of an insufficient mitral and/or tricuspid heart valve and reduction of valve regurgitation through the fixed approximation of the valve leaflets. Disposable devices associated with implantation (e.g., clip delivery system and accessories) may be included. Recheck?? | **Class D** |
| 212 | Heart valve prosthesis holder | A surgical instrument intended to hold a cardiac (heart) valve prosthesis or a cardiac annuloplasty ring at, or in proximity to, its site of implantation during surgery. It includes an implant mounting/containing feature and a handle; implantable devices are not included. | **Class A** |
| 213 | Heart valve prosthesis tester, single-use | A pen-like device intended to be used to manually manipulate a heart valve prosthesis to perform an assessment of the valvular prosthesis (e.g., its ability to open and close) prior to implantation and/or when in situ. | **Class C** |
| 214 | Heart-lung bypass unit tube | A tube will be placed in your heart to drain blood to the machine. | **Class C** |
| 215 | Hemoconcentrator set | A hemoconcentrator is a fluid removal device used during cardio bypass surgery. The device is inserted into the extracorpeal circuit where it acts to control hemodilution, maintain hematocrit levels and reduce the need for additional blood products during and after surgery. | **Class D** |
| 216 | His bundle detector | A device intended to detect disorders of impulse conduction in the bundle of His (atrioventricular) from the atrium to the cardiac ventricle. | **Class C** |
| 217 | Impedance cardiac output unit (Impedance cardiography) | A device intended to quantify cardiac output from measurements of the thoracic impedance changes associated with cardiac activity. | **Class B** |
| 218 | Impedance cardiograph | An electrocardiograph used to record variations in chest electric impedance generated by myocardial activity. | **Class B** |

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| 219 | Implantable cardiac device management application software | An application software program intended to be used in the management of an implantable cardiac device (e.g., monitor, pulse generator, pacemaker, defibrillator) by enabling computer-assisted functionality typically in one or more of the following areas: device programming; device function analysis; data extraction, storage, analysis and/or transfer; and clinical consultation/intervention planning. | **Class D** |
| 220 | Implantable cardiac monitor | A device intended to be implanted to monitor, record, and store electrocardiographic signals to help diagnose and monitor cardiac arrhythmias and/or acute coronary syndrome (ACS) changes. | **Class D** |
| 221 | Implantable cardiac monitor (ICM) programmer/transmitter/ alarm | A device designed to be operated by a clinician or patient to non-invasively change the settings (e.g., turn on/off) of an implantable cardiac monitor (ICM), and/or extract data from the implant, and/or provide an alarm function; it is not intended to communicate with a therapeutic cardiac implant. | **Class D** |
| 222 | Implantable pacemaker analyzer, intraoperative | An electronic instrument intended to test an implanted cardiac pacemaker, including the lead/tissue interface at the time of implantation, for invasive pacemaker evaluation and/or during electrophysiology (EP) diagnostic procedures. | **Class C** |
| 223 | Implantable pulse generator mesh bag, bioabsorbable | An implantable woven/knitted or porous bag made from a bioabsorbable synthetic polymer(s) intended to envelop an implantable pulse generator (IPG) (e.g., cardiac pacemaker/defibrillator, neurostimulator) to stabilize the implant in the subcutaneous pocket in which it is implanted. | **Class D** |
| 224 | Implantable pulse generator mesh bag, non-bioabsorbable | An implantable woven/knitted or porous bag made from a non-bioabsorbable synthetic polymer(s) intended to envelop an implantable pulse generator (IPG) (e.g., cardiac pacemaker/defibrillator) to stabilize the implant in the subcutaneous pocket in which it is implanted; it does not contain an antimicrobial agent. | **Class D** |
| 225 | Implantable vascular closure clip | A non-bioabsorbable metallic clip intended to be implanted following a percutaneous catheterization procedure to close the punctured access site on an artery (typically femoral) and improve haemostasis. | **Class D** |

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| 226 | Implanted subcutaneous intravascular port and catheter | The device allows for repeated access to the vascular system for the infusion of fluids and medications and the sampling of blood. | **Class C** |
| 227 | Intra-aortic balloon | An intra-aortic balloon is a prescription device that consists of an inflatable balloon, which is placed in the aorta to improve cardiovascular functioning during certain life-threatening emergencies, and a control system for regulating the inflation and deflation of the balloon. | **Class C** |
| 228 | Intra-aortic balloon control system (balloon pump) | An intra-aortic balloon control system, which monitors and is synchronized with the electrocardiogram, provides a means for setting the inflation and deflation of the balloon with the cardiac cycle. | **Class B** |
| 229 | Intra-aortic system balloon and control | It is a mechanical device that increases myocardial oxygen perfusion while at the same time increasing cardiac output. | **Class B** |
| 230 | Intracardiac catheter-tip electrode | An electrode located at one end of an appropriate flexible catheter (not included) intended to be inserted into the chambers of the heart to detect the presence of certain indicators to measure cardiac output. It may also be used to characterize the electrical activity of the heart. | **Class D** |
| 231 | Intracardiac circulatory assist axial-pump catheter (intracardiac pump) | A device with a built-in electrically-powered axial flow pump, inended to provide circulatory assistance to the heart by pumping blood during heart failure. It is typically used emergently post acute myocardial infarction (AMI), electively for high-risk cardiac catheterization, for open chest surgery, and/or during transport between hospitals. | **Class D** |
| 232 | Intracardiac circulatory assist axial-pump catheter control unit | A device intended to operate and monitor an intracardiac circulatory assist axial-pump catheter (e.g., a catheter with integrated micro motor and impeller) to provide circulatory assistance to the heart by pumping blood during heart failure. It is typically used emergently [e.g., post acute myocardial infarction (AMI)] or electively when haemodynamic support is necessary. | **Class D** |
| 233 | Intracardiac oximeter | A device that measures the oxygen saturation of blood pumped from the heart to the lungs (SvO2-venous oxygen saturation). | **Class C** |

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| 234 | Intracardiac pacemaker | A hermetically-sealed pulse generator that may be impregnated with a steroid (e.g., dexamethasone) and intended to be implanted with a catheter, via transvenous access, into the right ventricle (i.e., single-chamber pacing) of an arrhythmic heart to generate/conduct electrical impulses to improve cardiac output. | **Class D** |
| 235 | Intracardiac pacemaker extraction catheter | It is a steerable device intended to be introduced into the right ventricle of the heart to remove an implanted intracardiac pacemaker; it may also be used to remove an intracardiac pacemaker that has migrated to the peripheral vasculature. | **Class D** |
| 236 | Intracardiac pacemaker programming interface unit | An external device intended to interface a dedicated patient lead (cable with skin surface electrodes) with a pacemaker programmer (from which it draws its power), to enable noninvasive interrogation and programming of an implanted intracardiac pacemaker using high frequency electrical pulses (as an alternative to wireless communication); it is also intended to collect electrocardiogram (ECG) data for observation of pacemaker function. | **Class D** |
| 237 | Intracardiac ultrasound imaging catheter, steerable | A steerable device intended for intracardiac echocardiography to enable intracardiac and possibly great vessel (e.g., pulmonary artery) visualization for the assessment of cardiac anatomy and physiology, and visualization of other devices in the heart; it is not intended for peripheral vascular or coronary artery insertion/imaging. | **Class D** |
| 238 | Intraluminal artery stripper | An intraluminal artery stripper is a device used to perform an endarterectomy (removal of plaque deposits from arteriscleroticarteries.) | **Class D** |
| 239 | Intravascular anastomosis occluder/vascular plug | A device designed to temporarily occlude the flow of blood in the lumen of a blood vessel at a vascular anastomosis, primarily to control bleeding and enable operative field visualization during peripheral vascular bypass grafting and vessel repair surgery. | **Class D** |
| 240 | Intravascular diagnostic catheter | Used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels. | **Class D** |
| 241 | Intravascular extraction catheter-snare | A flexible device intended to be introduced into a blood vessel or similar structure to manually retrieve or manipulate a foreign body. | **Class C** |

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| 242 | Intravascular lithotripsy system balloon catheter, coronary | An electrically-powered device intended to be introduced into a coronary artery stiffened by a highly calcified atheromatous plaque, to transmit ultrasound (US) waves [e.g., acoustic pressure pulses] for the disruption of the plaque to improve vessel compliance. | **Class D** |
| 243 | Intravascular occluding catheter | It is a catheter with an inflatable or detachable balloon tip that is used to block a blood vessel, to treat malformations, e.g., aneurysms of intracranial blood vessels. | **Class D** |
| 244 | Intravenous catheter | A catheter that is inserted into a vein for supplying medications or nutrients directly into the bloodstream or for diagnostic purposes such as studying blood pressure. | **Class C** |
| 245 | Introducer sheath | Intended to provide easier access to the femoral, popliteal and infrapopliteal arteries. | **Class C** |
| 246 | Invasive arterial pressure cardiac output/oximetry monitor | It is intended to continuously measure and display arterial pressure cardiac output (APCO) [minimally-invasive cardiac output estimation from arterial blood pressure waveforms] and haemoglobin oxygen saturation (e.g., SpO2). | **Class C** |
| 247 | Invasive blood pressure monitor | A device that measures blood pressure invasively in an artery, and processes and displays the data. | |
| 248 | Laser blood flowmeter | A device that measures blood flow velocity using laser techniques, noninvasively or invasively, to identify impairment of blood flow (e.g., thrombus, stenosis, mechanical injury), and supports evaluation of the degree of the impairment. | **Class C** |
| 249 | Laser Sheath | Intended for use as adjuncts to conventional lead extraction tools in patients suitable for transvenous removal of chronically implanted pacing or defibrillator leads constructed with silicone or polyurethane outer insulation. | **Class C** |
| 250 | Long-term sphygmomanometer data recorder/Telemetric sphygmomanometer | A device intended to be carried by the patient to record long-term (24 hours) blood pressure. | **Class B** |
| 251 | Lymphangiography kit | A collection of devices intended to be used to inject a contrast medium into lymphatic vessels for their radiographic visualization. It typically includes a needle, tubing, and connectors. | **Class C** |

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| 252 | Magnetocardiograph | A device that uses superconducting sensor technology (a SQUID fluxmeter) to measure noninvasively the weak magnetic field generated on the surface of the chest in association with cardiac activity and analyze the data for diagnostic use. | **Class B** |
| 253 | Manual external defibrillator | An external pulse generator (EPG) intended to deliver electrical shocks to defibrillate the heart (restore normal rhythm) in a procedure initiated by a healthcare professional operator who monitors an electrocardiogram (ECG) to determine when to treat life-threatening arrhythmias (ventricular fibrillation and pulseless ventricular tachycardia) in sudden cardiac arrest (SCA) patients. | **Class C** |
| 254 | Mechanical atherectomy system, coronary, battery/line-powered | An assembly of devices intended to mechanically disrupt/remove atheroma plaque from the walls of coronary arteries. | **Class D** |
| 255 | Micro-catheter | It is intended to access the peripheral and neurovasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and or diagnostic materials such as contrast media. | **Class D** |
| 256 | Mitral annuloplasty ring | A circular band intended to be implanted in the heart to support a mitral valve annulus for the reconstruction and/or remodelling of an insufficient and/or stenotic mitral valve. | **Class D** |
| 257 | Mitral bi-leaflet mechanical heart valve prosthesis | An artificial substitute for a natural mitral heart valve intended to be implanted during open heart surgery typically to treat acquired or congenital valvular disease. | **Class D** |
| 258 | Mitral heart valve bioprosthesis | A xenograft (e.g., porcine or bovine heart valve) intended to be implanted in a patient during open heart surgery to repair or replace a dysfunctional mitral heart valve. | **Class D** |
| 259 | Mitral transcatheter heart valve bioprosthesis | An implantable xenograft (e.g., bovine) intended to be used to repair/replace a stenosed or regurgitant mitral heart valve, or previously-implanted mitral heart valve prosthesis, and which is implanted with a catheter via percutaneous access (e.g., transfemoral, transapical) while the heart is beating. | **Class D** |
| 260 | Mitral/tricuspid annuloplasty ring, open-surgery | A circular band intended to be implanted in the heart during open heart surgery to support a mitral or tricuspid valve annulus for the reconstruction and/or remodelling of | **Class D** |

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| | | insufficient and/or stenotic mitral or tricuspid valves. | |
| 261 | MRI-conditional, implantable defibrillator/pacing lead (Endocardial defibrillation lead) | An MR-conditional, implantable flexible wire with an electrode, intended to function as an electrical conductor to transmit defibrillation impulses from an implanted cardioverter-defibrillator (ICD) [automatic implantable cardioverter-defibrillator (AICD)] to the endocardium of the right ventricle. It may also be intended to transmit pacing impulses from a cardiac resynchronization therapy (CRT) pulse generator, AICD, or other pacing device. | **Class D** |
| 262 | Multifunction cardiac electrode, adult/pediatric | A device intended to be applied to an adult/pediatric patient for automatic or manual defibrillation, external pacing, cardioversion, and electrocardiographic monitoring through transmission of cardiac bioelectric signals (typically from the thoracic surface) to devices that record/process the signals and potentially return electrical impulses. | **Class C** |
| 263 | Multiple lumen catheter | Intended for monitoring central venous pressure (CVP), sampling blood, and simultaneous administration of multiple IV solutions or drugs. | **Class B** |
| 264 | Neonatal electrocardiographic electrode | A non-sterile electrical conductor intended to be applied to a neonatal patient to transmit electrical signals from the body surface to a data measuring/display device (typicaly an electrocardiograph, patient monitor, or patient monitoring system) to produce an electrocardiogram (ECG). | **Class B** |
| 265 | Non-central circulatory angiopolygraph | A device to examine vascular hemodynamics except in the heart. | **Class B** |
| 266 | Non-indwelling blood flow transducer | A device intended for measuring blood flow externally (extravascularly). The device is used together with a blood flowmeter. The device may also measure the blood flow either inside the heart or over the outside of a blood vessel. | **Class C** |
| 267 | Noninvasive multiple cardiovascular measurement unit | This unit is intended for noninvasive measurement of multiple cardiovascular parameters [including electrocardiogram (ECG), phonocardiogram (PCG), carotid pulse tracing, femoral pulse tracing and four limb pulse tracing/blood pressure] to assist in the diagnosis of cardiac and/or peripheral vascular disease. | **Class C** |

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| 268 | Oximetry catheters, Oximetry Paceport catheter | It is indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, continuous mixed venous catheter oxygen saturation monitoring, and for infusing solutions. | **Class D** |
| 269 | Pacemaker generator function analyzer | A pacemaker generator function analyzer is a device that is connected to a pacemaker pulse generator to test any or all of the generator's parameters, including pulse duration, pulse amplitude, pulse rate, and sensing threshold. | **Class C** |
| 270 | Pacemaker lead adaptor | A pacemaker lead adaptor is a device used to adapt a pacemaker lead so that it can be connected to a pacemaker pulse generator produced by a different manufacturer. | **Class C** |
| 271 | Pacemaker repair or replacement material | A pacemaker repair or replacement material is an adhesive, a sealant, a screw, a crimp, or any other material used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker pulse generator. | **Class D** |
| 272 | Pacing cardiac catheter | A flexible tube equipped with an electrode on the distal end. The electrode is inserted into the heart to control the heart rate. | **Class D** |
| 273 | Pacing lead extraction kit, single use/reusable | A collection of devices intended to remove the electrically-conducting leads of an implantable pacemaker or an implantable cardioverter-defibrillator (ICD). It typically includes stylets, dilating sheaths, snares, and retrieval baskets. | **Class D** |
| 274 | Pacing lead implantation adapter/Flushing tool | A sterile device intended to be connected to one end of a compatible cardiac pacing lead containing a lumen for over-guidewire implantation, to enable flushing of the lumen (typically with heparinized saline) and aid insertion of a guidewire during implantation. It is not implantable. | **Class C** |
| 275 | Pacing system analyzer | A pacing system analyzer (PSA) is a prescription device that combines the functionality of a pacemaker electrode function tester and an external pacemaker pulse generator (EPPG). It is intended to supply an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and intracardiac R-wave potential. | **Class C** |

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| 276 | Pacing/defibrillation lead cap | An implantable device intended to cover and protect the lead terminals of an implantable pacing device (e.g., an implanted pacemaker or defibrillator) during the implantation procedure, or to isolate (cap) any lead terminals that are not used. This device is implanted with the pacemaker or defibrillator system. | **Class D** |
| 277 | Pacing/defibrillation lead cap kit | A collection of various implantable pacing lead caps intended to cover and protect the lead terminals of an implantable pacing device (e.g., an implanted pacemaker or defibrillator) during the implantation procedure, or to isolate (cap) any lead terminals that are not used. | **Class D** |
| 278 | Pacing/defibrillation lead electrical adapter | An implantable device intended to adapt the electrical connectors of an implanted pacemaker and/or defibrillator pacing lead to a non-compatible pacemaker or defibrillator (i.e., when they do not meet connection design). This device is implanted with the pacemaker or defibrillator system. | **Class D** |
| 279 | Pacing/defibrillation lead electrical extension adapter | An implantable device intended to provide a functional and modified connection between existing pacing leads (e.g., IS-1 leads) and an implantable pacing/defibrillation device (e.g., pacemaker, defibrillator). It consist of extension leads to increase the reach of the pacing leads. | **Class D** |
| 280 | Pacing/defibrillation lead extraction expander | A device intended to dilate the end of a cut implantable pacemaker or implantable cardioverter-defibrillator (ICD) lead, typically to enable correction of any deformities to the lead, allowing for accurate lead sizing with a gauge in preparation for lead extraction. | **Class A** |
| 281 | Pacing/defibrillation lead extraction extender | A device intended to be used during the release and removal of a cut implantable pacemaker or implantable cardioverter-defibrillator (ICD) lead, of the solid type (lumenless), from surrounding tissue during lead extraction. | **Class A** |
| 282 | Pacing/defibrillation lead extraction stylet | It is a lead extraction accessory intended to be used to debride foreign matter from inside the lead body and may be used to measure the length of the lead after connector has been removed. | **Class A** |

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| 283 | Pacing/defibrillation lead extraction wrap | A sterile device intended to be used to aid the release and removal of a cut implantable pacemaker or implantable cardioverter-defibrillator (ICD) lead (hollow coil type) by wrapping around and binding the proximal components of the lead and/or other lead extraction/extension device (e.g., pacing lead stylet). | **Class A** |
| 284 | Pacing/defibrillation lead repair kit | A collection of sterile tools and materials intended to repair the lead of an implantable pacemaker or an implantable cardioverter-defibrillator (ICD). Typical components include a screwdriver, wrench, screws, crimps, adhesives, sealants, and other items used to repair a pacemaker lead or to reconnect a pacemaker/defibrillator lead to a pacemaker/defibrillator generator. | **Class C** |
| 285 | Pacing/defibrillation lead repair tool | A dedicated device, typically designed as a wrench or a screwdriver, intended to repair the lead of an implantable pacemaker or an implantable cardioverter-defibrillator (ICD). It may also be used to reconnect a pacemaker/defibrillator lead to a pacemaker/defibrillator generator. | **Class A** |
| 286 | Pacing/defibrillation lead setscrew | A sterile device intended to connect and secure the attached pacing lead terminal(s) in the connection socket of an implantable pacing device (e.g., an implanted pacemaker or defibrillator) during the implantation procedure. | **Class A** |
| 287 | Pacing/defibrillation lead stylet | It is intended to be percutaneously inserted into the coronary venous vasculature to aid in the transvenous placement and/or removal of implantable pacemaker/defibrillator leads; it may in addition be intended to extract an indwelling catheter or other foreign object. | **Class D** |
| 288 | Pacing/defibrillation lead suture sleeve | It is intended to function as a channel for an implantable electrical stimulation lead (e.g., pacing lead, defibrillation lead, neurostimulation lead) to allow the surgeon to suture the lead to the patient's tissue to prevent it from moving after the implantation procedure is completed. It may be implanted with the electrical stimulator, pacemaker or defibrillator system. | **Class D** |

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| 289 | Pacing/defibrillation lead suture tunneller | A hand-held manual surgical instrument designed to create a tunnel (an artificial passageway) through subcutaneous tissue for the placement of an implantable extracardiac lead/electrode. It may include an integrated sheath (e.g., split sheath) intended to assist lead placement. | **Class B** |
| 290 | Patient monitoring system module, cardiac output | It is intended for the measurement of cardiac output (the volume of blood pumped by the heart per minute) obtained through a pressure transducer/catheter introduced into a blood vessel. It is designed to operate as part of a patient monitoring system enhancing the function of this system (the parent device). | **Class C** |
| 291 | Patient monitoring system module, electrocardiographic | A small unit intended for the detection, measurement, and recording of the electrical activity of the heart in the form of an electrocardiogram (ECG) obtained through cables/leads connected to the patient. It is designed to operate as part of a patient monitoring system enhancing the function of this system (the parent device). | **Class B** |
| 292 | Patient monitoring system module, electrocardiographic, telemetric | This unit is intended for receiving (and displaying) wireless electrocardiogram (ECG) signals sent from an ambulatory patient so that the electrical activity of the patient's heart can be monitored when the patient is remote to the patient monitoring system. It is designed to operate as part of a patient monitoring system enhancing the function of this system (the parent device). | **Class B** |
| 293 | Patient monitoring system module, electrocardiographic/respiratory | This unit is intended for the measurement of the electrical activity of the heart in the form of an electrocardiogram (ECG) and to follow patient respiration patterns to identify episodes of arrhythmia and/or apnoea also derived from the ECG. It is designed to operate as part of a patient monitoring system enhancing the function of this system (the parent device). | **Class C** |
| 294 | Percutaneous catheter | A needle catheter getting access to a blood vessel, followed by the introduction of a wire through the lumen (pathway) of the needle. | **Class D** |
| 295 | Percutaneous intravascular long term catheter | The device allows for repeated access to the vascular system for long-term use for 30 days or more, and it is intended for administration of fluids, medications, and nutrients; the<br>sampling of blood, etc. | **Class B** |

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| 296 | Pericardiocentesis catheter | It is intended for the drainage of effusion from the pericardial sac (the pericardium). It may also be used for the irrigation/instillation of drugs (e.g., antibiotics, cytotoxic agents) into the pericardium. | **Class D** |
| 297 | Pericardiocentesis needle, reusable | It is intended for the puncture of the pericardial cavity for the aspiration (removal) of fluids (pericardiocentesis). | **Class D** |
| 298 | Pericardiocentesis needle, single-use | It is intended for the puncture of the pericardial cavity for the aspiration (removal) of fluids (pericardiocentesis). | **Class D** |
| 299 | Pericardium drainage catheter | Intended for drainage of the pericardium. | **Class D** |
| 300 | Peripheral angioplasty balloon catheter, basic | A non-drug-eluting device intended for percutaneous transluminal angioplasty (PTA) to dilate a stenotic peripheral (i.e., non-cerebral, non-coronary) artery by controlled inflation of a distensible balloon(s) at its distal tip; it may also be intended for positioning and expansion of a stent/stent-graft. | **Class C** |
| 301 | Peripheral angioplasty balloon catheter, drug-coated | It is intended for percutaneous transluminal angioplasty (PTA) to dilate a stenotic peripheral (i.e., non-cerebral, non-coronary) artery by controlled inflation of a distensible balloon(s) at its tip, and to simultaneously release a drug intended to inhibit restenosis; it may also be intended for positioning and expansion of a stent/stent-graft. | **Class D** |
| 302 | Peripheral stent system | It is intended to be placed in the peripheral arteries that supply blood into body organ. | **Class D** |
| 303 | Peripherally-inserted central venous catheter | It is intended to be introduced into a peripheral vein and advanced to a central vein for short- to long-term intravascular access to administer medications (antibiotics), chemotherapeutic agents, nutrients, parenteral solutions, pain management fluids, and sometimes for blood sampling, monitoring of blood pressure and temperature, and for power injection of contrast media; it is not primarily intended for extracorporeal blood therapies such as haemodialysis. | **Class C** |
| 304 | Phonocardiograph | A device that records and detects heart sounds on the body surface using vibrations caused by cardiac activity and transmitted to the body surface via the organs and tissues. | **Class B** |

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| 305 | Phonocardiograph/pulse wave unit | This device is intended to simultaneously record the electrocardiogram, combined with the carotid pulse wave, apex beat, digital pulse volume, phonocardiogram, etc. by connecting to the electrocardiograph or the electrocardiographic analysis system. | **Class B** |
| 306 | Pressure transducer dome, single use/reusable | A device (dome) to be connected with a pressure transducer to form a measurement system, for invasive blood pressure measurement or cerebrospinal fluid pressure measurement. Some types of device incorporate a stopcock and flushing device. | **Class B** |
| 307 | Pressure transducer, single use/reusable | A device used to convert pressure into electric signals to display on the base unit. | **Class B** |
| 308 | Pulmonary arterial shunt | A small vascular graft used for bypassing a stenotic pulmonary artery. | **Class D** |
| 309 | Pulmonary heart valve bioprosthesis | A xenograft (e.g., porcine or bovine heart valve) intended to be implanted in a patient during open heart surgery to repair/replace a dysfunctional pulmonary heart valve, or to replace a pulmonary valve in patients undergoing a pulmonary autograft (Ross) procedure. | **Class D** |
| 310 | Pulmonary transcatheter heart valve bioprosthesis | An implantable xenograft (e.g., bovine, porcine) intended to be used to repair/replace a stenosed or regurgitant pulmonary heart valve prosthesis (previously implanted), or native pulmonary valve anatomy that may have been surgically repaired, and which is designed to be implanted with a catheter via vascular access. | **Class D** |
| 311 | Retrieval snare | Intended for use in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and central circulatory system and the extracranial neurovascular anatomy. | **Class C** |
| 312 | Retrieval snare, non central circulatory | Intended for use in the retrieval and manipulation of atraumatic foreign bodies located in the vasculature other than coronary and central neurovascular anatomy. | **Class D** |
| 313 | Scalp vein set | Intended to be used for insertion into the patient's vascular system as an in-dwelling device to administer fluids intravenously or to sample blood. | **Class C** |

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| 314 | Self-expandable heart valve bioprosthesis collapsing tool | A manually-operated device intended to reduce the diameter of a self-expanding cardiac valve prosthesis during open and/or transcatheter cardiovascular surgery so the collapsed valve can be mounted onto a dedicated holder or catheter to facilitate implantation. | **Class A** |
| 315 | Self-expandable heart valve prosthesis collapsing tool base | It is to intended to function as a sturdy support (base) for a self-expanding cardiac valve prosthesis collapsing tool during the implantation procedure. | **Class A** |
| 316 | Self-expandable heart valve prosthesis post-dilation balloon catheter | It is intended to be used during open cardiovascular surgery to dilate the inflow ring of a sutureless cardiac (heart) valve prosthesis, after its implantation and self expansion, to facilitate valve sealing and anchoring. | **Class C** |
| 317 | Semi-automated external defibrillator, non-rechargeable/rechargeable | This electronic device is intended to automatically detect cardiac arrhythmias (ventricular fibrillation/pulseless ventricular tachycardia) in a sudden cardiac arrest (SCA) patient, and to audibly/visually instruct an operator to enable it to activate defibrillation of the heart or allow the operator to decide when to activate defibrillation based on its electrocardiogram display. | **Class C** |
| 318 | Single chamber implantable Defibrillator/Cardioverter defibrillator | An implantable pulse generator (IPG) with a cardiac rhythm recognition system, intended to deliver an electrical impulse(s) to defibrillate the heart (restore normal rhythm) or slow a rapid heart rate, and typically to pace a slow heart rate. It is commonly known as an automatic implantable cardioverter-defibrillator (AICD). It may be MR conditional. | **Class D** |
| 319 | Single-chamber implantable defibrillator | An implantable pulse generator (IPG) with a cardiac rhythm recognition system, to analyse an electrocardiogram (ECG) with lead(s) inside or on one heart chamber, intended to deliver an electrical impulse(s) to defibrillate the heart (restore normal rhythm) or slow a rapid heart rate, and typically to pace a slow heart rate. | **Class D** |

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| 320 | Single-chamber implantable pacemaker, fixed rate/demand | A battery-powered, implantable device consisting of a hermetically-sealed pulse generator with a single-chamber pacing lead and intended to generate and conduct electrical impulses to the heart typically when the heart beats too slowly (bradycardia) or has other abnormal rhythms (arrhythmias). It may provide constant electrical stimuli to normalize the heartbeat (fixed-rate) and/or provide a stimulus only when electrical activity within the heart is sensed to be abnormal (demand); it is not intended for defibrillation therapy. | **Class D** |
| 321 | Single-chamber implantable pacemaker, rate-responsive | A battery-powered, implantable device consisting of a hermetically-sealed pulse generator with a single-chamber pacing lead and intended to generate and conduct electrical impulses to an abnormal heart to adjust its rate of contraction to meet the body's increased need for blood flow due to activity by sensing changes in the body (e.g., motion, breathing frequency), etc. It is not intended to provide defibrillation therapy. | **Class D** |
| 322 | Single-chamber pacemaker, rate-responsive | A device implanted beneath the skin of the chest with a pacing lead in or on one chamber of the heart (right atrium or ventricle) and intended to generate and conduct electrical impulses to an abnormal heart to adjust its rate of contraction to meet the body's increased need for blood flow due to activity. It is not intended for defibrillation. It may be MR conditional. | **Class D** |
| 323 | Subclavian catheter | Catheters intended to be placed in veins in the neck (internal jugular vein), chest (subclavian vein or auxiliary vein), etc. | **Class C** |
| 324 | Suction ablation catheter system | Intended for inactivating portions of the heart's conduction system to prevent abnormal heartbeat rates, comprising a tubular body having an open, distal end and a proximal aperture for applying suction through the catheter and through the distal end. | **Class C** |
| 325 | Surgical intravascular shunt | It is intended to temporarily channel (shunt) intravascular blood through a vascular anastomosis, primarily to control bleeding and enable distal perfusion during coronary or peripheral vascular bypass grafting and vessel repair surgery. | **Class C** |

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| 326 | Surgical microscope fluorescent angiography system | A device assembly intended for viewing intraoperative blood flow in the cerebral vascular area, in bypass grafts during coronary artery bypass graft (CABG) surgery, and during plastic and reconstructive surgery. | **Class B** |
| 327 | Telemetric electrocardiographic ambulatory recorder (Holter monitor) | It is intended to be worn by a patient during daily activities for 24-hour recording of the electrocardiographic signals of the heart, for the diagnosis of cardiac disorders (e.g., arrhythmias). The device may include surface electrodes, lead wires and accessories intended for attachment/removal (e.g., wipes, adhesive remover). | **Class B** |
| 328 | Temporary cardiac pacing (balloon) catheter | It is intended to deliver temporary pacing stimuli to the heart and may detect bioelectric signals from the heart. It is used: 1) in an emergency during bradycardia or asystole until a pacemaker can be implanted to control the heart rate; 2) during and/or after surgery; or 3) during cardiac catheterization [e.g., electrophysiological (EP) examinations]. | **Class D** |
| 329 | Thermal-dilution cardiac output unit | A unit that is intended to measure the blood flow from the heart using the indicator dilution technique, in which a thermal indicator (e.g., cold saline solution or other indicator solution) is injected upstream of the heart and monitored on the downstream side by a balloon-tipped (flow-directed) catheter with a temperature probe. | **Class C** |
| 330 | Thrombectomy catheter | Thrombectomy catheter is specifically designed to treat deep vein thrombosis (DVT) in large-diameter upper and lower peripheral veins. | **Class D** |
| 331 | Transcatheter heart valve bioprosthesis implantation catheter | It is intended to be used to deploy and implant a heart valve bioprosthesis (not included) during a minimally invasive transcatheter procedure via transarterial access (e.g., femoral, subclavian, aortic) under fluoroscopic guidance. | **Class D** |
| 332 | Transoesophagal pacing lead | It is intended to regulate cardiac pacing, with one end connected to an external temporary pacemaker and the other end (electrode) applied through the oesophagus to the heart. | **Class C** |
| 333 | Transtelephonic implantable pacemaker analysis system | An assembly of devices designed to analyse the performance of an implanted pacemaker based on electrocardiographic measurements that can be monitored transtelephonically. | **Class C** |

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| 334 | Transthoracic pacing lead | It is intended as an electrical conductor between the heart and an external temporary pacing/defibrillation device used to treat postoperative cardiac arrhythmias/cardiac arrests. The electrode end is attached to the myocardium. This device is only used for temporary pacing of the heart. | **Class C** |
| 335 | Tricuspid transcatheter heart valve bioprosthesis | An implantable xenograft (e.g., bovine) intended to be used to repair/replace a stenosed or regurgitant tricuspid heart valve, or previously-implanted tricuspid heart valve prosthesis, and which is implanted using a catheter via percutaneous access (e.g., transfemoral, transapical) while the heart is beating. | **Class D** |
| 336 | Ultrasonic blood flowmeter | A noninvasive, or invasive ultrasonic Doppler device for blood flow measurement, intended for the identification of various blood flow disorders, e.g., thrombosis. | **Class C** |
| 337 | Valve prosthesis rotator | A surgical device used during heart valve replacement surgery for changing direction of the flow in an artificial valve. | **Class C** |
| 338 | Varicose vein adhesive-treatment kit (Venous adhesive occlusion system) | A collection of devices intended to be used for the endovascular closure of the great saphenous vein (GSV) and associated varicosities as a treatment for varicose veins. It typically includes a surgical adhesive (e.g., cyanoacrylate), syringe, delivery catheter, dilator, introducer and a dispensing gun. | **Class D** |
| 339 | Vascular embolization device | It is an intravascular implant intended to control hemorrhaging due to aneurysms, certain types of tumors. | **Class D** |
| 340 | Vascular graft extraluminal mesh-sleeve, coronary | A non-bioabsorbable implantable device intended to be used for the extraluminal (external) support of a coronary artery bypass graft (CABG) [e.g., saphenous vein graft]. | **Class D** |
| 341 | Vascular graft with bovine-derived valve | A device that combines a bovine-derived valve with a bovine cervical vein or artificial blood vessel used for pulmonary artery replacement (including re-replacement).Usually intended for treatment of congenital heart abnormalities. | **Class D** |
| 342 | Vascular irrigation cannula, cardiac vessel graft | A device intended to be used during cardiac surgery to flush an autologous graft, typically a section of explanted saphenous vein, to test its integrity and the closure of lateral vessels, as well as to remove debris and clots after resection. | **Class B** |

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| 343 | Vascular irrigation cannula, coronary artery, reusable/single-use | It is intended to be surgically inserted, temporarily, into a coronary artery to serve as a channel for the transport of fluid during a surgical intervention. | **Class C** |
| 344 | Vectorcardiograph | An electrocardiograph (ECG) device intended to record a series of changes in the magnitude and direction (vector) of the potential in a complete cardiac cycle. | **Class B** |
| 345 | Vectorcardiograph/ECG electrode | It is intended to be applied to the surface of the body to transmit the electrical signal at the body surface to a recording and monitoring device that produce an electrocardiograph or vectorcardiogram. | **Class B** |
| 346 | Vein ablation device | It is a non-thermal, minimally-invasive device intended for treating the source of varicose veins, providing patients with an immediate recovery and a return to normal daily routines | **Class C** |
| 347 | Vena cava filter extraction/repositioning kit | A collection of sterile devices designed to perform the percutaneous retrieval or repositioning of an implanted inferior vena cava (IVC) filter. | **Class D** |
| 348 | Vena cava filter, permanent/temporary | A vascular device intended to be percutaneously implanted in the inferior vena cava (IVC) to prevent pulmonary embolism (PE); it can be retrieved before a threshold period or remain as a permanent implant after the period. | **Class D** |
| 349 | Ventricular bypass (assist) device | A ventricular bypass (assist) device is a device that assists the left or right ventricle in maintaining circulatory blood flow. The device is either totally or partially implanted in the body. | **Class D** |
| 350 | Vessel dilator for percutaneous catheterization | A vessel dilator for percutaneous catheterization is a device which is placed over the guide wire to enlarge the opening in the vessel, and which is then removed before sliding the catheter over the guide wire. | **Class C** |
| 351 | Wearable neonatal heart rate meter | An electrically-powered device intended to detect and display the heart rate of a neonate, typically within the first few hours after delivery. | **Class B** |

# Name of Category: Neurological

# Total No. of Devices: 202

## Category: Neurological

| S. No. | Device name | Intended use | Risk Class |
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| 1 | Analgesic PENS system | Intended to deliver controlled electrical impulses directly to the subcutaneous tissue (i.e., invasively) in the vicinity of a peripheral nerve as relief of chronic neuropathic pain. | **Class B** |
| 2 | Analgesic TENS system | Intended to reduce the perception of/treat pain by transcutaneous electrical stimulation on peripheral nerves. It is intended to treat pain from surgery, trauma, musculoskeletal problems/arthritis, bursitis, dental problems, etc., and may be used in physical therapy and during labour/delivery. | **Class B** |
| 3 | Analytical non- scalp cutaneous lead | Intended to conduct electrical signals between a skin electrode(s) or needle electrode(s) [electrode not included] and a device designed for electrophysiological recording/monitoring [e.g., electromyography (EMG), evoked potentials (EP), bioelectrical impedance]. | **Class A** |
| 4 | Analytical non-scalp cutaneous electrode | Electrical conductor designed to be attached to the skin surface of a patient outside of the hair line (i.e., non-scalp) to conduct electrical signals to a parent device for electrophysiological recording/monitoring. | **Class A** |
| 5 | Analytical scalp electrode, single use/reusable | Intended to be attached to the scalp surface of a patient to transmit changes in the electrical potential of various areas of the brain for recording/monitoring by a connected parent device [i.e., an electroencephalograph (EEG), sleep, or evoked potential recording device]. | **Class B** |
| 6 | Analytical scalp lead | Intended to connect an electroencephalographic electrode(s) to an electroencephalographic system to facilitate the transmission of the electrical signals during encephalography (EEG). | **Class B** |
| 7 | Aneurysm clip | An aneurysm clip is a device used to occlude an intracranial aneurysm (a balloonlike sac formed on a blood vessel) to prevent it from bleeding or bursting. | **Class D** |

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| 8 | Antibiotic impregnated Hydrocephalous Catheter | It is intended for use in the treatment of hydrocephalous as a component of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated. | **Class D** |
| 9 | Anti-nausea transcutaneous electrical nerve stimulation wristband | An electrically-powered device intended to be worn on the wrist of a patient to apply electrical stimuli to the median nerve through the skin (transcutaneously), to help relieve the sensation of nausea caused by various conditions [e.g., pregnancy (morning sickness), motion (travel sickness), chemotherapy]. | **Class B** |
| 10 | Antiseizure/psychiatric-therapy vagus nerve electrical stimulation system | Implantable device intended to apply periodic electrical stimuli to the vagus nerve to help control seizures and/or to help treat psychiatric disorder symptoms (e.g., depression). | **Class D** |
| 11 | Atrial cerebrospinal fluid catheter | Intended to be implanted as the distal component of a ventriculoatrial shunt to channel cerebrospinal fluid (CSF) to the right atrium where it can be absorbed into the body. | **Class D** |
| 12 | Autonomic neuropathy heart rate meter | Intended to diagnose autonomic nervous system dysfunction (autonomic neuropathy) | **Class C** |
| 13 | Balloon catheter for cranial angioplasty | It is intended for angioplasty of intra- and extra-cranial arteries harbouring untreated stenoses, or recurrent stenoses after angioplasty and/or stenting of flow diverter deployment. It may also be used for dilatation of insufficiently adapted stents and flow diverters | **Class D** |
| 14 | Balloon for Cerebrovascular Occlusion | Balloon used to treat blockage or closing of cerebrovascular occlusion vessels/carotid arteries. | **Class D** |
| 15 | Bare-metal intracranial vascular stent | Intended to be implanted into the base or parent artery of an intracranial aneurysm to facilitate the delivery of embolics to fill the aneurysm, facilitate clotting within the aneurysm by slowing blood flow into it, and/or to provide support for a neurovascular embolization coil placed inside the aneurysm. | **Class D** |
| 16 | Behavioural therapy electrical stimulation system | Intended in the treatment of obsessive/compulsive behaviour and drug abuse, by applying electrical impulse (aversion therapy). | **Class C** |
| 17 | Bladder/bowel-evacuation implantable electrical stimulation system | Intended to empty the urinary bladder and/or the bowels by applying electrical stimuli typically to the cone- | **Class D** |

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| | | shaped end of the spinal cord (conus medularis). | |
| 18 | Block-monitoring peripheral nerve electrical stimulation system | An assembly of battery-powered devices intended to apply electrical stimuli to a peripheral nerve (e.g., the ulnar or lower extremity nerve) to assess the adequacy of neuromuscular block during surgery, and its reversal during the recovery period. | **Class C** |
| 19 | Blood pressure/neuromuscular transmission monitoring cuff extension tubing/cable | A length of pneumatic tubing with an integrated electrical cable intended to be connected to the existing tubing/cable of a blood pressure/neuromuscular transmission monitoring cuff (not included) to increase its length, during combined intraoperative noninvasive blood pressure (NIBP) and neuromuscular transmission (NMT) monitoring. This is a reusable device. | **Class B** |
| 20 | Brain biopsy procedure kit | A packaged collection of sterile equipment that includes a disposable brain biopsy needle and other supplies intended to be used to perform a stereotaxic sampling of brain tissue. This is a single-use device. | **Class C** |
| 21 | Brain injury adjunctive interpretive electroencephalograph assessment aid | A brain injury adjunctive interpretive electroencephalograph assessment aid is a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the structural condition of the patient's brain in the setting of trauma. A brain injury adjunctive interpretive EEG assessment aid is for use as an adjunct to standard clinical practice only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis. | **Class C** |
| 22 | Brain-responsive electrical stimulation system | Intended to continuously monitor brain activity and deliver electrical stimuli to seizure foci in response to neurological disorders (e.g., epilepsy). | **Class D** |
| 23 | Cardiac-therapy vagus nerve electrical stimulation system | Intended to apply periodic stimuli to the vagus nerve as a treatment for cardiac failure. | **Class D** |

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| 24 | Central Nervous System Shunt Catheters including Neurological catheters and other Components | It is a device or combination of devices used to divert fluid from the brain or other part of the central nervous system including an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial pressure or fluid volume. | **Class D** |
| 25 | Cerebral oximeter | A mains electricity (AC-powered) photoelectric device that noninvasively measures the brain tissue blood oxygen saturation and venous oxygen saturation in the brain. It is typically used as an adjunct monitor for the regional haemoglobin oxygen saturation of blood in the brain of a paediatric or adult patient. | **Class C** |
| 26 | Cerebral oximeter sensor, single use | A photoelectric device designed to be applied externally to the scalp/head of a patient for transcutaneous measurement [e.g., using near-infrared spectroscopy (NIRS)] of brain tissue blood oxygen saturation and/or venous oxygen saturation in the brain. | **Class C** |
| 27 | Cerebral perfusion catheter | Intended for brain protection during profound hypothermic circulatory arrest during aortic surgery. | **Class D** |
| 28 | Cerebrospinal fluid catheter tubing set | A sterile two-way tubing with a stopcock designed to connect the proximal end of a cerebrospinal fluid (CSF) drainage catheter directly to a drainage bag or an intracranial pressure monitor via a Luer connection. | **Class A** |
| 29 | Cerebrospinal fluid external drainage kit | A collection of sterile devices intended to be used with an intracerebral or spinal infusion/drainage catheter (not included) to collect drained cerebrospinal fluid (CSF) from the brain ventricles or from the lumbar subarachnoid (intrathecal) region as a means of reducing CSF volume and intracranial pressure (ICP). It typically includes devices such as a drip chamber, drainage bag, tubing set, catheter connector, stopcock, and filter. | **Class A** |
| 30 | Cerebrospinal fluid manometer | Intended to measure the cerebrospinal fluid (CSF) pressure/intracranial pressure via lumbar puncture. | **Class C** |

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| 31 | Cerebrospinal fluid shunt adaptor | A sterile device intended to enable connection of a cerebrospinal fluid (CSF) shunt or shunt component (e.g., cerebrospinal fluid catheter) to a syringe during shunt patency checking; it is not intended to be implanted. | **Class B** |
| 32 | Cerebrospinal fluid shunt connector | An implantable device intended to create a fluid path connection between components of a cerebrospinal fluid (CSF) shunt assembly (e.g., lumbar and/or peritoneal catheters of a ventriculoperitoneal or lumboperitoneal shunt), designed to remove excess cerebrospinal fluid from around the central nervous system especially in the treatment of hydrocephalus. | **Class D** |
| 33 | Cerebrospinal fluid shunt valve | An implantable device intended to function as part of a lumboperitoneal, ventriculoperitoneal or ventriculoatrial shunt to regulate the pressure and flow level of cerebrospinal fluid (CSF) from the lumbar spine or brain to the peritoneum/heart right atrium in the management of increased intracranial pressure (e.g., caused by hydrocephalus). | **Class D** |
| 34 | Cerebrospinal fluid shunt valve programmer | Intended to noninvasively modify the operating pressure of a programmable, non-active, implanted cerebrospinal fluid (CSF) shunt valve that is part of a CSF shunt. | **Class C** |
| 35 | Cochlear nerve function operative test electrode | An invasive, hand-held, thin instrument (probe) with a distal electrode intended for preoperative and/or intraoperative delivery of electrical stimulation to the cochlear (auditory) nerve to assess nerve function prior to implantation of a cochlear implant (CI). | **Class B** |
| 36 | Coma-arousal vagus nerve electrical stimulation system | Intended to apply periodic stimuli to the vagus nerve for the purpose of exciting the patient to arousal from a vegetative state (i.e., a deep coma). | **Class D** |
| 37 | Cortical electrode/subdural electrode | A cortical electrode is an electrode which is temporarily placed on the surface of the brain for stimulating the brain or recording the brain's electrical activity. | **Class D** |

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| 38 | Cranial bone flap fixation clip | A sterile, non-bioabsorbable device intended to be partially implanted around the perimeter of a replaced cranial bone flap after a craniotomy to ensure structural stability during the healing period. It may also be used for craniofacial bone fracture fixation. | **Class D** |
| 39 | Cranial bone prosthesis | An implantable device intended to repair a defect of the cranium or mandible as prescribed by a healthcare provider for a specified patient. The device may be used to repair defects due to injury, surgical intervention for tumour removal, congenital anomaly, or disease, or for cosmetic/aesthetic purposes. | **Class D** |
| 40 | Cranial bur | Intended to fit into an appropriate powered handpiece that provides the rotation allowing the user to excavate soft or hard skull tissue. | **Class B** |
| 41 | Cranial electrotherapy stimulator | A cranial electrotherapy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety | **Class D** |
| 42 | Cranial perforator | Metallic rotary endpiece designed to cut a hole(s) or a circular section(s) of the skull vault (calvarium) by attaching to powered drill/handpiece. | **Class B** |
| 43 | Cranial port/reservoir (Cerebrospinal fluid shunt port/reservoir) | A sterile, implantable chamber intended to be connected to an intracerebral catheter for infusion/injection of materials (e.g., chemotherapeutic agents, radioisotopes) into the brain (e.g., cerebral ventricles, cystic tumours, tumour cavities); it may also be used for drainage of cerebrospinal fluid (CSF) from the ventricles and as part of a ventriculo-peritoneal/atrial shunt system. | **Class D** |
| 44 | Cranial resinous compound | A substance used to reconstitute cranial bone after neurosurgery (i.e., cranioplasty). It may be conformed as an inert implant in an appropriate shape (e.g., a plate) needed to repair the defect of the skull, either using an intraoperatively cured solid composition, or a preoperatively fabricated, porous, custom-made, implant. | **Class D** |
| 45 | Cranial trephine | Intended as a neurosurgical blade used to cut/remove circular sections of the skull vault (calvarium) to provide access to the interior. | **Class B** |

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| 46 | Craniotomy power tool system handpiece | Intended to be used to rotate a cranial cutting tool (i.e., a drill bit, bur, trephine or perforator) in order to produce a hole or holes in the skull vault (calvarium). | **Class C** |
| 47 | Cryogenic surgical device | A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in nervous tissue by the application of extreme cold to the selected site. | **Class D** |
| 48 | Cutaneous electrode | A cutaneous electrode is an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation. | **Class B** |
| 49 | Deep brain electrical stimulation system | Designed to apply electrical stimuli to specific areas of the deep brain for the treatment of movement disorders, psychiatric disorders and/or to treat chronic, severe, intractable pain. The pulse generator may be implanted in the sternum. | **Class D** |
| 50 | Deep brain electrical stimulation system lead | Intended to be implanted in specific areas of the deep brain and used along with deep brain electrical stimulation system. | **Class C** |
| 51 | Depth electrode | A depth electrode is an electrode used for temporary stimulation of, or recording electrical signals at, subsurface levels of the brain. | **Class D** |
| 52 | Diagnostic peripheral nerve electrical stimulation system | Intended to apply electrical stimuli in one peripheral region of the body while the response is monitored in another peripheral region. It is intended to be used for the stimulation of a peripheral nerve or muscle in nerve conduction studies performed during clinical electrophysiology (EP) assessments. | **Class C** |
| 53 | Diagnostic somatosensory tactile stimulation system | Intended to be used to apply tactile stimuli to the body (e.g., pneumatic activation of a membrane to the fingers and lips) typically for evoked response procedures to investigate the function and potential disorders of the brain. | **Class B** |
| 54 | Diskectomy system, percutaneous, automatic | Intended for the percutaneous (through the skin) removal of the nucleus pulposus from the lumbar disc. | **Class D** |
| 55 | Dura mater sealant | Intended to be applied to sutured dura mater to prevent | **Class C** |

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| | | cerebrospinal fluid (CSF) leakage during healing. | |
| 56 | Echoencephalograph | An echoencephalograph is an ultrasonic scanning device (including A-scan, B-scan, and doppler systems) that uses noninvasive transducers for measuring intracranial interfaces and blood flow velocity to and in the head | **Class C** |
| 57 | Ejaculation electrical stimulation system | Intended to apply electrical stimuli to the nerves that control ejaculation. | **Class C** |
| 58 | Electroconvulsive therapy system | Intended to apply strong electrical stimuli to a patient's brain to induce convulsions and loss of consciousness, typically to treat major depression, schizophrenia, or mania. | **Class D** |
| 59 | Electroencephalogram (EEG) signal spectrum analyzer | An electroencephalogram (EEG) signal spectrum analyzer is a device used to display the frequency content or power spectral density of the electroencephalogram (EEG) signal. | **Class B** |
| 60 | Electroencephalograph | An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head. | **Class C** |
| 61 | Electroencephalograph electrode/lead tester | An electroencephalograph electrode/lead tester is a device used for testing the impedance (resistance to alternating current) of the electrode and lead system of an electroencephalograph to assure that an adequate contact is made between the electrode and the skin. | **Class B** |
| 62 | Electroencephalograph test signal generator | An electroencephalograph test signal generator is a device used to test or calibrate an electroencephalograph. | **Class B** |
| 63 | Electroencephalograph tester | Intended to perform quality control procedures on an electroencephalograph (EEG) machine and/or a sleep recording machine. | **Class A** |
| 64 | Electroencephalographic electrode cap | Analytical scalp electrodes preconfigured within a head- worn device to use with electroencephalography (EEG). | **Class B** |
| 65 | Electroencephalographic long-term ambulatory recorder | Intended to continuously record electroencephalographic signals in ambulatory patients for periods usually from 24 to 72 hours to assess a variety of neurological conditions (e.g., epilepsy) and psychiatric disorders. | **Class B** |

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| 66 | Electroencephalographic monitoring system | Intended to continuously measure the electrical signals produced by a patient's brain and display/record them as an electroencephalogram (EEG) to evaluate brain function. Alongwith which measuring of other physiological parameters such as electromyogram (EMG), respiration wave forms, blood pressure, ocular motility, and/or haemoglobin oxygen saturation (SpO2) and carbon dioxide (CO2) in relation to EEG. | **Class C** |
| 67 | Electromyograph | Intended in clinical diagnosis of muscular disorders to evaluate muscle weakness and to determine if the weakness is related to the muscles themselves or a problem with the nerves that supply the muscles. | **Class B** |
| 68 | Electromyograph cable/lead, sterile | An insulated metal wire(s) intended to conduct electrical signals between a skin electrode(s) or needle electrode(s) [electrode not included] and electromyography (EMG) monitoring device. | **Class A** |
| 69 | Electromyograph electrode catheter | Intended to be used to monitor electrical activity in muscles of different target areas (other than the brain and heart), such as urethra, oesophagus, diaphragm, etc. | **Class C** |
| 70 | Electromyograph electrode/Electromyograph needle electrode | A sterile electrical conducting device designed to be inserted percutaneously into muscle or nerve tissue to detect bioelectrical signal activity. It is not primarily intended for nerve stimulation. | **Class B** |
| 71 | Electromyography monitor | An electrically-powered device designed to continuously measure electrical signals from a patient's skeletal muscle and display/record the signals as an electromyograph (EMG) to evaluate brain/nerve function, typically during a surgical procedure. It may also include data interpretation and/or telemetry features. | **Class C** |
| 72 | Electronystagmograph | Intended for detecting the electrical potential caused by eye movements. | **Class B** |
| 73 | Epicranial brain electrical stimulation system | Intended to apply weak, pulsed (not continuous) electrical stimuli from beneath the scalp to specific areas of the brain for the treatment of focal epilepsy. | **Class D** |

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| 74 | Esthesiometer | An esthesiometer is a mechanical device which usually consists of a single rod or fiber which is held in the fingers of the physician or other examiner and which is used to determine whether a patient has tactile sensitivity | **Class A** |
| 75 | Evoked-potential graphic recording system | An assembly of devices intended for assessing brain and sensory function by recording a localized electrical potential from the brain or spinal cord in response to stimulation (i.e., visual, auditory, and/or somatosensory) of the sensory organs, or of some point along the ascending pathway from the sensory organs, or within the central nervous system. | **Class C** |
| 76 | Extramuscular diaphragm/phrenic nerve electrical stimulation system | Intended to provide ventilatory support to a patient with diaphragm dysfunction of neuromuscular origin through electrical stimulation of the phrenic nerve, to contract the diaphragm rhythmically (using extramuscular electrodes) and cause the patient to draw breath in a manner similar to natural breathing. | **Class D** |
| 77 | Eye-tracking neurological/brain injury assessment device | An electrically-powered unit intended to measure and analyse eye movement to assist in the diagnosis/assessment of a neurological disorder [e.g., autism spectrum disorder (ASD), attention-deficit hyperactivity disorder (ADHD), dementia] or potential traumatic brain injury (e.g., concussion). | **Class B** |
| 78 | Facial nerve locating system | Intended to locate a facial nerve by applying an electrical stimulus. | **Class B** |
| 79 | Facial nerve-locating system | It is intended to locate a facial nerve by applying an electrical stimulus with a probe and comparing muscle responses as the probe is moved. It is used during diagnosis and assessment of nerve function, to locate nerves during surgery reducing the chance of accidental injury, and to monitor the progress of nerve regeneration after surgery. | **Class B** |

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| 80 | Flexible fibreoptic epiduroscope | An endoscope with a flexible inserted portion intended for the visual examination and treatment of intractable back and leg pain (e.g., chronic lumbago or sciatica). This device is intended to facilitate and/or perform perfusion or wash in the epidural space, dissect epidural adhesions, or deliver medications. | **Class C** |
| 81 | Gait- enhancement electrical stimulation system, external | Intended to improve the gait in a patient suffering from partial paralysis of the lower extremities or other neuromuscular disorders by applying external electrical simulation. | **Class B** |
| 82 | Gait-enhancement electrical stimulation system, implantable | Intended to improve the gait in a patient suffering from partial paralysis of the lower extremities or other neuromuscular disorders by applying internal electrical simulation. | **Class D** |
| 83 | Home seizure monitoring system | Intended to detect and record a seizure by continuous measurement of one or more physical/physiological parameters (e.g., body motion, electrical activity of the heart or skeletal muscles) in a patient with epilepsy during daily activities and/or sleep in the home; some types may also be used in clinical settings. | **Class C** |
| 84 | Human dura mater | Human dura mater is human pachymeninx tissue intended to repair defects in human dura mater | **Class D** |
| 85 | Implantable intracerebral cannula | A sterile, implantable tube intended to be surgically placed in a specific area of the brain (e.g., basal ganglia) to position a deep brain electrical stimulation lead/electrode, using a stereotactic surgery system, and to function as a guide for subsequent and regular placement and/or removal of the lead/electrode. It may include a stylet/trocar blade. | **Class D** |
| 86 | Implantable pulse generator mesh bag, bioabsorbable | Intended to envelop an implantable pulse generator (IPG) (e.g., cardiac pacemaker/defibrillator, neurostimulator) to stabilize the implant in the subcutaneous pocket in which it is implanted. | **Class D** |
| 87 | Implantable spinal cord electrical stimulation system programmer | Device designed to change, telemetrically, one or more of the operating parameters (the programs) of an implanted spinal cord electrical stimulation system pulse generator (EPG). | **Class C** |

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| 88 | Implanted cerebellar stimulator | An implanted cerebellar stimulator is a device used to stimulate electrically a patient's cerebellar cortex for the treatment of intractable epilepsy, spasticity, and some movement disorders. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's cerebellum and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver. | **Class D** |
| 89 | Implanted diaphragmatic/phrenic nerve stimulator | An implanted diaphragmatic/phrenic nerve stimulator is a device that provides electrical stimulation of a patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation (a state in which an abnormally low amount of air enters the lungs) caused by brain stem disease, high cervical spinal cord injury, or chronic lung disease. | **Class D** |
| 90 | Implanted intracerebral/sub cortical stimulator for pain relief | An implanted intracerebral/subcortical stimulator for pain relief is a device that applies electrical current to subsurface areas of a patient's brain to treat severe intractable pain. | **Class D** |
| 91 | Implanted neuromuscular stimulator | An implanted neuromuscular stimulator is a device that provides electrical stimulation to a patient's peroneal or femoral nerve to cause muscles in the leg to contract, thus improving the gait in a patient with a paralyzed leg. | **Class D** |
| 92 | Implanted spinal cord stimulator for bladder evacuation | An implanted spinal cord stimulator for bladder evacuation is an electrical stimulator used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is unable to empty his or her bladder by reflex means or by the intermittent use of catheters. | **Class D** |
| 93 | Intracerebral catheter cranial-fixation kit | A collection of sterile devices intended to be used to affix an intracerebral sensor/infusion/drainage catheter on the skull of a patient. It includes cranial screws and screwing tools; it does not include the intracerebral catheter, and does not include devices intended for long-term implantation (> 30 days). | **Class D** |

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| 94 | Intracerebral catheterization drill bit | A sterile drilling endpiece intended to be used for drilling the skull of a patient to facilitate the introduction and fixation of an intracerebral sensor/infusion/drainage catheter. It is intended to be attached to a manual or electric drilling device. | **Class B** |
| 95 | Intracerebral infusion/drainage catheter, long term (Ventricular catheter) | It is intended to be surgically inserted through the skull for long-term (> 30 days) subdural access to the brain (e.g., cerebral ventricles, cystic tumours) for cerebrospinal fluid (CSF) drainage and/or infusion of materials (e.g., chemotherapeutic agents); it is typically used for measurement of intracranial pressure (ICP) and as part of a shunt system. | **Class D** |
| 96 | Intracerebral infusion/drainage catheter, short term | A flexible tube intended to be surgically inserted through the skull for short-term (= 30 days) subdural access to the brain (e.g., cerebral ventricles, cystic tumours) for cerebrospinal fluid (CSF) drainage and/or infusion of materials (e.g., chemotherapeutic agents); it may also be intended for measurement of intracranial pressure (ICP). | **Class D** |
| 97 | Intracerebral sensor catheter | It is intended to be surgically inserted through the skull for access to the ventricular and/or parenchymal areas of the brain to measure intracranial parameters [e.g., intracranial pressure (ICP), temperature, partial pressure of oxygen (pO2)]; it may in addition be intended for cerebrospinal fluid (CSF) drainage and/or infusion of materials (e.g., chemotherapeutic agents, radioisotopes). | **Class D** |
| 98 | Intracerebral trocar blade | A hand-held, manual surgical instrument with a sharp, needle-like point intended to be used in conjunction with an intracerebral catheter (e.g., ventricular catheter) to puncture tissue and create a channel to access the brain (e.g., cerebral ventricles, cystic tumours) typically for cerebrospinal fluid (CSF) drainage or infusion of materials (e.g., chemotherapeutic agents). | **Class B** |
| 99 | Intracranial catheter holder, sterile | It is intended to secure an intracranial catheter (e.g., intracerebral sensor catheter, intracerebral infusion/drainage catheter, epidural sensor catheter) to the skin; it may | **Class B** |

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| | | also be used as a marker for the planned depth of the catheter insertion. | |
| 100 | Intracranial catheter navigation stylet | It is a guiding stylet which may or may not be connected to an electromagnetic (EM) coil to enable navigated placement and insertion of ventricular catheters or shunts during neurosurgery. | **Class D** |
| 101 | Intracranial pressure monitor device | Intended for intermittent or continuous measurement and display of intracranial pressure (ICP). It is used in conjunction with an invasive intracranial device. | **Class D** |
| 102 | Intracranial/compartmental-pressure monitor calibrator/cable | An electronic device intended to generate a reference baseline for the standardization of readings of intracranial pressure (ICP) and/or pressure in a muscle compartment, and to transfer the readings from a catheter (i.e., intracerebral sensor or compartmental-pressure catheter) to a pressure monitor. | **Class B** |
| 103 | Intramuscular diaphragm/phrenic nerve electrical stimulation system | Intended to provide ventilatory support to a patient with diaphragm dysfunction of neuromuscular origin through electrical stimulation of the phrenic nerve to contract the diaphragm rhythmically (using intramuscular electrodes) and cause the patient to draw breath in a manner similar to natural breathing. | **Class D** |
| 104 | Intramuscular diaphragm/phrenic nerve electrical stimulation system programmer | Intended to change, telemetrically, one or more of the operating parameters (the programs) of an intramuscular diaphragm/phrenic nerve electrical stimulation system external pulse generator (EPG). | **Class C** |
| 105 | Intranasal cooling system | Intended for rapid cooling induction in patients where temperature reduction is clinically indicated (e.g., following a cerebral ischemic event, during cardiac arrest) to help mimimize damage to the brain and heart. | **Class C** |
| 106 | Intrathecal infusion pump, implantable | A device designed to be implanted in a patient for the storing and subarachnoid (intrathecal) administration of narcotics/drugs to manage intractable pain and muscle spasms of malignant or nonmalignant origin. | **Class D** |

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| 107 | Invasive- detection physiological monitor | Intended for continuous or intermittent measurement, display and/or recording of several invasively-detected physiological parameters [e.g., intracranial pressure (ICP), compartmental pressure]. | **Class C** |
| 108 | Leukotome | Intended to cut brain tissue (i.e., cutting white matter, leukotomy). | **Class B** |
| 109 | Lumbar cerebrospinal fluid drainage catheterization kit | A collection of sterile devices intended for short-term percutaneous access to the subarachnoid (intrathecal) or epidural space of the lumbar spinal column to drain cerebrospinal fluid (CSF) as a means of reducing CSF volume and intracranial pressure (ICP). It includes a spinal infusion/drainage catheter and devices intended for catheter insertion (e.g. Tuohy needle, suture, guidewire) and CSF collection (e.g., drip chamber, drainage bag, tubing set, filter). | **Class D** |
| 110 | Lumboperitoneal shunt | An implantable device intended to divert excessive cerebrospinal fluid (CSF) from the subarachnoid space of the lumbar spine to the peritoneal cavity where it can be absorbed into the body, as a treatment for raised CSF pressure (e.g., caused by hydrocephalus). | **Class D** |
| 111 | Lumboperitoneal shunt peritoneal catheter | A component of a lumboperitoneal (LP) shunt intended to channel cerebrospinal fluid (CSF) to the peritoneal cavity, where it can be absorbed into the body, in the management of elevated intracranial pressure due to increased CSF (hydrocephalus). | **Class D** |
| 112 | Lumboperitoneal shunt spinal catheter | A component of a lumboperitoneal (LP) shunt intended to channel cerebrospinal fluid (CSF) from the subarachnoid space of the lumbar spine in the management of elevated intracranial pressure due to increased CSF (hydrocephalus). | **Class D** |
| 113 | Magnetoencephalography system | Intended to non-invasively detect, measure, and display bio- magnetic signals produced by electrically-active cortical brain tissue, and that provide diagnostic information about the location of the active tissue responsible for cognitive brain functions relative to the surrounding brain anatomy. | **Class B** |

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| 114 | Manual cranial rotary handpiece, single-use | A manually-powered, hand-held, surgical device intended to be used to remove circular sections of the skull vault (calvarium) to provide access to the interior for diagnosis (e.g., the insertion of a neuroscope), or treatments [e.g., to alleviate intracranial pressure (ICP)], or for the removal of a bone flap for brain surgery. This is a single-use device. | **Class B** |
| 115 | Manual surgical saw, flexible, single use | Intended for cutting bone through a sawing action during neurological or orthopaedic surgery. | **Class B** |
| 116 | Meningeal prosthesis | Intended to repair the meningeal membrane (meninges). | **Class D** |
| 117 | Migraine-therapy peripheral nerve electrical stimulator | A portable electrically-powered device intended to non-invasively stimulate a peripheral nerve(s) [including vagus nerve] in the neck, trunk or extremity to treat or prevent symptoms of migraine/headaches. it may be used in conjunction with a smartphone and may be operated by a patient or healthcare provider in the home and healthcare facility. | **Class B** |
| 118 | Nasopharyngeal electrode | A nasopharyngeal electrode is an electrode which is temporarily placed in the nasopharyngeal region for the purpose of recording electrical activity | **Class C** |
| 119 | Needle electrode | A needle electrode is a device which is placed subcutaneously to stimulate or to record electrical signals. | **Class C** |
| 120 | Nerve conduction velocity measurement device | It is intended to measure nerve conduction time by applying a stimulus, usually to a patient's peripheral nerve. | **Class C** |
| 121 | Nerve guide, bioabsorbable, animal-derived | Collagen matrix material intended to be used to create a tunnel through which a discontinuous peripheral nerve can regenerate to bridge the proximal and distal nerve stumps. | **Class D** |
| 122 | Nerve guide, bioabsorbable, synthetic | Synthetic material intended to be used to create a tunnel through which a discontinuous peripheral nerve can regenerate to bridge the proximal and distal nerve stumps. | **Class D** |
| 123 | Nerve guide, non-bioabsorbable | Non-bioabsorbable material intended to be used to create a tunnel through which a discontinuous peripheral nerve can regenerate to bridge the proximal and distal nerve stumps. | **Class D** |

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| 124 | Nerve location/function operative test pulse generator | An electrically-powered unit intended to produce electrical signals for preoperative and/or intraoperative application of electrical stimulation, via a connected hand-held probe with distal electrodes (not included), to a neural tissue site to: 1) locate nerves during surgery to prevent unintentional injury; 2) diagnose or assess nerve function; and/or 3) help determine an optimal electrical stimulation site prior to implantation of an active implant [e.g., cochlear implant (CI), auditory brainstem implant (ABI)]. It does not display electromyography (EMG) readings. | **Class C** |
| 125 | Nerve transcutaneous ultrasound ablation system | Intended to thermally ablate nerves using ultrasound to relieve chronic pain caused by conditions such as arthritis, bone metastases, sacroilitis, etc. | **Class C** |
| 126 | Nerve-function monitor | It is intended to continuously assess the adequacy of the nerve function of a non-ambulatory patient who requires monitoring (e.g., as a result of trauma, anaesthesia, intervention, evaluation). It typically monitors evoked potential (EP), electromyography (EMG), electroencephalography (EEG) and/or neuromuscular block response. | **Class C** |
| 127 | Nerve-locating anaesthesia needle | A sterile, electrically-insulated needle intended to be used with a syringe and pulse generator to function as: 1) an electrode during nerve/nerve plexus location; and 2) as a conduit for administration of a local anaesthetic during peripheral nerve-blocking. | **Class C** |
| 128 | Nerve-locating system (Intraoperative nerve monitor) | A multicomponent assembly of electrically-powered devices intended to locate a nerve by applying an electrical stimulus with a probe and observing muscle responses. It does not display electromyography (EMG) readings. It is used during nerve function assessment and/or intraoperatively to locate nerves to reduce accidental injury. | **Class B/C** |

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| 129 | Nerve-locating system probe, reusable/single use | A hand-held surgical instrument intended to function as an electrical conductor to locate a nerve during open surgery, and for diagnostic purposes [electromyography (EMG), cortical mapping], by delivering controlled electrical impulses to a specific body site for the measurement of a neural response. This is a reusable device intended to be sterilized prior to use. | **Class C** |
| 130 | Neural-tissue balloon catheter | It is intended for the compression or dilation of neural tissue under direct endoscopic or fluoroscopic vision typically for the treatment of trigeminal neuralgia. It may be supplied with a stylet. | **Class D** |
| 131 | Neurological endoscope | A neurological endoscope is an instrument with a light source intended for the visual examination and treatment of the brain (e.g., ventricles, hydrocephalus) and/or spine and contents. | **Class C** |
| 132 | Neurological stereotactic surgery system | An assembly of devices intended for precisely positioning probes, other instruments, or implantable devices during neurosurgery. The system may include computerized functions to store diagnostic images used for image-guided surgery. Intended to store diagnostic images used for image-guided neurosurgery. | **Class C** |
| 133 | Neuromuscular motion disorder ambulatory recorder/analyser | An assembly of devices intended for 24-hour recording of body movements of a patient affected by a neuromuscular kinetic disorder (e.g., Parkinson's disease) for analysis. | **Class B** |
| 134 | Neuromuscular rehabilitation software | A software program intended to be used by a patient whose neuromuscular abilities have been impaired by a disease/condition (e.g., Parkinson's, stroke, traumatic brain injury) to help train and regain neuromuscular control (e.g., balance, strength, speech) through guided activities (e.g., visuomotor stimulating onscreen patterns, tailored exercise regimes, interactive games). It is intended to be used on a non-medical computerized device (e.g., tablet, smartphone) for use in the home; it is not intended to interface with external biomechanical function analysis equipment. | **Class B** |

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| 135 | Neuromuscular transmission electrical skin sensor | Intended to detect electrical neuromuscular transmission (NMT) signals, for assessing the degree of neuromuscular block in a patient. | **Class C** |
| 136 | Neuromuscular transmission electrode | A non-sterile electrical conductor designed to be applied to a patient's body surface, typically the forearm or ankle, to deliver stimulating electrical pulses to a motor nerve or measure electrical impulses from the nerve during neuromuscular transmission (NMT) monitoring. This is a single-use device. | **Class B** |
| 137 | Neuromuscular transmission electrode/sensor lead | An insulated metal wire(s) designed to conduct electrical signals between neuromuscular transmission (NMT) electrodes and sensors placed on a patient's body and a patient monitoring system module, intended for the monitoring of patient relaxation to determine the level of neuromuscular block and the localization of a nerve in an area of the body. | **Class B** |
| 138 | Neuromuscular transmission lead set, reusable | A device(s) intended exclusively to conduct electrical neuromuscular transmission (NMT) signals to/from an array of neuromuscular electrodes attached to the surface of the skin of the hand and forearm, or the foot. The patient-contact electrodes are not included. | **Class B** |
| 139 | Neuromuscular transmission motion sensor | Intended to be placed on the thumb and index finger of a patient to detect movements and convert them into electrical neuromuscular transmission (NMT) signals during nerve stimulation. | **Class B** |
| 140 | Neuromuscular transmission regional anaesthesia block adaptor | A device intended to conduct electrical signals between an integrated electrode connection clip and an injection needle on a patient’s body, via a neuromuscular transmission (NMT) sensor cable, and subsequently to a patient monitoring module for the localization of a nerve in an area of the body for the administration of regional anaesthesia. | **Class B** |

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| 141 | Neurophysiologic monitoring system | It is intended to monitor and provide electrical stimuli to spinal nerves or other neural pathways (may include the brain) during intraoperative surgery or intensive care, typically to reduce the incidence of accidental injury during instrumented spine surgery, or to diagnose acute dysfunction in corticospinal conduction (e.g., due to traction, shearing, laceration, compression, or vascular insufficiency). It typically displays electroencephalogram (EEG), electromyogram (EMG), and/or evoked responses. | **Class C** |
| 142 | Neuropsychiatric interpretive electroencephalograph assessment aid | The neuropsychiatric interpretive electroencephalograph assessment aid is a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the patient's neuropsychiatric condition. The neuropsychiatric interpretive EEG assessment aid is used only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis. | **Class C** |
| 143 | Neurosurgical bone flap elevator | A hand-held, manually-operated surgical instrument intended to be used to pry up, lift, and position a bone flap in a neurosurgical procedure upon the skull. | **Class B** |
| 144 | Neurosurgical curette, single-use | A hand-held manual surgical instrument intended to be used to scrape and debride tissue from a bone surface (e.g., cancellous vertebral bone of the spine) or a cavity wall during a neurosurgical procedure.It is typically used during percutaneous kyphoplasty to treat vertebral compression fractures (VCFs), or during craniotomy or brain microsurgery. | **Class B** |
| 145 | Neurosurgical head holder (skull clamp) | A neurosurgical head holder (skull clamp) is a device used to clamp the patient's skull to hold head and neck in a particular position during surgical procedures. | **Class B** |

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| 146 | Neurosurgical micro targeting drive | A calibrated guide mechanism used by a surgeon to manually operate a Z-axis positioner which allows extremely accurate placement of a single or multiple microelectrodes, stimulation electrodes, probes, instruments, or implantable devices, along a chosen track during neurosurgery on the brain. It is intended to be used with a neurosurgical stereotactic system. | **Class B** |
| 147 | Neurosurgical microscope | Designed to magnify minute structures within the neurological fields for surgery, typically the brain or spine or surroundings in the performance of neurological surgical procedures which require high magnification by transmitted light. | **Class B** |
| 148 | Neurosurgical probe | A hand-held manual surgical instrument designed for exploring/dissecting intracranial structures during a surgical procedure. | **Class B** |
| 149 | Neurosurgical procedure kit, non-medicated, reusable | A collection of various manual neurosurgical instruments, dressings and the necessary materials used to perform a neurosurgical procedure. It does not contain pharmaceuticals. | **Class B** |
| 150 | Neurosurgical procedure kit, non-medicated, single-use | A collection of various sterile, manual neurosurgical instruments, dressings and the necessary materials used to perform a neurosurgical procedure. It does not contain pharmaceuticals. | **Class B** |
| 151 | Neurosurgical retraction cannula | A single-lumen surgical device designed to be used with an obturator to atraumatically displace brain tissues without tissue penetration to create a surgical access corridor to a specific lesion/abnormality within the brain. It may include depth markings. This is a single-use device. | **Class C** |
| 152 | Neurosurgical retraction cannula manipulation tool | A hand-held, manual surgical device intended to be used to manipulate the position of a neurosurgical retraction cannula during brain surgery. It is intended to attach to the cannula. It is not intended to manipulate tissues directly. | **Class B** |
| 153 | Neurosurgical retraction cannula stabilization tool | A hand-held, manual surgical device intended to be used to stabilize the position of a neurosurgical retraction cannula during brain surgery. It is typically clamped to a retraction assembly. This is a single-use device. | **Class B** |

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| 154 | Neurosurgical retraction obturator | A hand-held manual surgical instrument intended to fill the lumen of a neurosurgical retraction cannula (not included) to facilitate atraumatic displacement of brain tissues and insertion of the retraction cannula during brain surgery. | **Class C** |
| 155 | Neurosurgical retraction obturator mounting rod (Navigation stylet) | A hand-held surgical device intended to be connected to a neurosurgical retraction obturator during brain surgery to allow mounting of devices (e.g., navigational devices) to the obturator/cannula assembly during introduction into brain tissues. It is not intended to manipulate tissues directly. | **Class C** |
| 156 | Neurosurgical retraction obturator/probe adaptor | A manual device intended to connect a neurosurgical retraction obturator to a probe (e.g., stereotactic/electromagnetic surgery system probe), typically of incompatible sizes. The obturator and probe are not included. | **Class A** |
| 157 | Neurosurgical retraction system, brain | A frame-like assembly of surgical instruments/devices intended to be used to create a self-locking, self-retaining mechanism dedicated to the temporary parting of brain tissue during neurosurgery. This may be a reusable device. | **Class B** |
| 158 | Neurosurgical retraction system, spinal | A frame-like assembly of surgical instruments/devices intended to be used to create a self-locking, self-retaining mechanism dedicated to the temporary parting of dorsal tissue to enable access for spinal surgery. This may be a reusable device. | **Class B** |
| 159 | Neurosurgical rongeur | A hand-held manual surgical instrument designed with a cutting/biting action used for the removal of bone, e.g., pieces of the skull, during a neurosurgical intervention. | **Class B** |
| 160 | Neurosurgical scissors | A hand-held manual surgical instrument designed to cut tissue (e.g., dura mater, neural soft-tissue) during neurosurgery. | **Class B** |
| 161 | Neurosurgical sponge | A sterile absorbent material intended to be used on the brain to remove blood and other fluids during an operation. This is a single-use device. | **Class C** |

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| 162 | Neurosurgical ultrasound navigation system | Intended for intraoperative imaging of the brain for precise navigation during brain surgery (e.g., resection of malignant brain tumours, treatment of vascular malformations). | **Class B** |
| 163 | Neurosurgical ultrasound navigation system optical tracking unit | A component of a neurosurgical ultrasound (US) navigation system used to track the position of all the localizers/spatial markers during intraoperative imaging and to supply the US system with valid positional data. | **Class B** |
| 164 | Neurosurgical ventricular access guide/Neurosurgical catheter guide | A device intended to guide a catheter into the brain. It can be used to place ventricular catheters or other catheters. | **Class D** |
| 165 | Neurovascular embolization coil | A non-bioabsorbable, implantable device intended to induce a neurovascular thrombosis to treat an intracranial aneurysm and/or neurovascular arteriovenous malformation (AVM); it may also be intended to treat non-neurovascular malformations. Disposable devices associated with implantation (e.g., delivery wire, catheter) may be included. | **Class D** |
| 166 | Neurovascular embolization plug | A non-bioabsorbable material (e.g., gel, liquid) intended to be implanted in a neurovascular blood vessel, to obstruct blood flow to treat a brain arteriovenous malformation (bAVM). It may be supplied as a liquid [e.g., ethylene vinyl alcohol (EVOH)], gel or powder intended to solidify or expand in situ to create a barrier to blood flow (embolus); it contains no pharmaceutical agents. It may be supplied with dedicated instruments for implantation. | **Class D** |
| 167 | Non-electroencephalogram (EEG) physiological signal based seizure monitoring system | A non-electroencephalogram (non-EEG) physiological signal based seizure monitoring system is a noninvasive prescription device that collects physiological signals other than EEG to identify physiological signals that may be associated with a seizure. | **Class C** |

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| 168 | Non-implantable intracerebral cannula, reusable/single use | A nonimplantable, rigid tube intended to be surgically inserted through the skull to access the brain (e.g., cerebral ventricles) for cerebrospinal fluid (CSF) drainage, infusion of materials, and/or for use as a port through which instruments, leads and/or probes can be passed to perform a variety of diagnostic, treatment, or surgical procedures. | **Class D** |
| 169 | Nonpowered neurosurgical instrument | A nonpowered neurosurgical instrument is a hand instrument or an accessory to a hand instrument used during neurosurgical procedures to cut, hold, or manipulate tissue. It includes specialized chisels, osteotomes, curettes, dissectors, elevators, forceps, gouges, hooks, surgical knives, rasps, scissors, separators, spatulas, spoons, blades, blade holders, blade breakers, probes, etc. | **Class B** |
| 170 | Olfactometry system | Intended to determine the response of humans to odours delivered through the nose, including irritants. | **Class C** |
| 171 | Opioid withdrawal/irritable bowel symptom-relief periauricular nerve percutaneous electrical stimulator | A body-worn, electronic device intended to provide percutaneous electrical nerve field stimulation (PENFS) applied close to cranial/peripheral nerves around the external ear to achieve remote symptom relief mediated by central nervous system (CNS) pathways and structures [e.g., amygdala, spinal cord neurons]. It may be used for opioid withdrawal symptoms (e.g., bone/joint aches, tremor, anxiety), or irritable bowel syndrome [IBS]-associated functional abdominal pain (FAP). | **Class C** |
| 172 | Patient monitoring system module, nerve location | Intended to be plugged into a parent patient monitoring device (not included) for the localization of a nerve in an area of the body. It is intended to be used during the administration of relaxants and local anaesthesia. | **Class C** |
| 173 | Peripheral nerve implantable analgesic electrical stimulation system and its components | The implantable system is intended to deliver episodic electrical stimulation to the epidural space in/near a peripheral nerve (e.g., in a limb) for the relief/treatment of acute and/or chronic intractable pain [e.g., chronic low back pain (CLBP)]. It may have an external control unit. | **Class C** |

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| 174 | Peritoneal/atrial cerebrospinal fluid catheter | A flexible tube intended to be implanted as the distal component of a ventriculo-peritoneal/atrial shunt, to channel cerebrospinal fluid (CSF) to either the peritoneal cavity or the right atrium (i.e., dual-capability) where it can be absorbed into the body. | **Class D** |
| 175 | Photodiode subretinal prosthesis system | Intended to provide visual function to a patient with vision loss due to retinal degeneration by detecting light, converting it into electrical signals, and relaying them to the retina for neural stimulation. | **Class C** |
| 176 | Physical therapy ultrasound/neuro muscular stimulation system | intended for the simultaneous delivery of ultrasound and electrical energies for physical therapy, typically to help prevent scar tissue formation in healing tissues and/or to help reduce muscle spasms and pain. It may also be used to promote the removal of metabolic by-products from injured muscles while applying ultrasound treatments. | **Class C** |
| 177 | Polysomnography analyser | A mains electricity (AC-powered) device designed to record and interpret a variety of physiologic functions during sleep to evaluate sleep/sleep-related disorders (e.g., insomnia, hypersomnia, apnoea). It typically performs electroencephalography, electrocardiography, electro-oculography, electromyography, and respiration, temperature, and pulse oximetry readings. It may also provide audiovisual information about the sleeping patient for behavioral analysis and other measurements (e.g., gastric reflux, bedwetting). | **Class B** |
| 178 | Rheoencephalograph | It is intended to estimate a patient's cerebral circulation (blood flow in the brain) by electrical impedance methods with direct electrical connections to the scalp or neck area. | **Class D** |
| 179 | Scalp clip | It is intended to stop bleeding during surgery on the scalp | **Class C** |
| 180 | Scoliosis- treatment electrical stimulation system | Intended to apply electrical stimuli to the spinal musculature to produce a force that stabilizes or limits the progression of the spinal lateral curvature (i.e., scoliosis). | **Class D** |
| 181 | Skull plate anvil | It is intended to be used to form alterable skull plates in the proper | **Class A** |

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| | | shape to fit the curvature of a patient's skull. | |
| 182 | Skull punch | It is intended to be used to punch holes through a patient's skull to allow fixation of cranioplasty plates or bone flaps by wire or other means | **Class B** |
| 183 | Skullplate screwdriver, reusable | It is intended to be used to fasten cranioplasty plates or skullplates to a patient's skull by screws. | **Class A** |
| 184 | Spinal cord nerve implantable analgesic electrical stimulation system and its components | The implantable system is intended to deliver episodic electrical stimulation to the epidural space of the spinal cord (e.g., lumbar, truncal) for the relief/treatment of acute and/or chronic intractable pain [e.g., chronic low back pain (CLBP)]. It may have an external control unit. | **Class D** |
| 185 | Spinal cord/peripheral nerve implantable analgesic electrical stimulation system control unit | A portable, external, electrically-powered component of a spinal cord/peripheral nerve implantable analgesic electrical stimulation system intended to be used by a patient to telemetrically control its function (on/off) for delivery of treatment cycles. | **Class C** |
| 186 | Spinal needle | It is intended to withdraw a sample of cerebrospinal fluid (CSF), assist introduction of a spinal guidewire or catheter (e.g., lumboperitoneal shunt, intrathecal catheter), and/or deliver contrast media and/or anaesthetic or analgesic agents intrathecally (subarachnoid) or into a vertebral disc, either directly or using the needle-through-needle technique. | **Class C** |
| 187 | Spinal port/catheter | An implantable device intended to provide access to the subarachnoid (intrathecal) space of the spinal column for infusion (e.g., chemotherapeutic agents, pain relieving drugs) and/or drainage [e.g., cerebrospinal fluid (CSF)]. | **Class D** |
| 188 | Spinal shaver system | A hand-held powered surgical instrument intended for bone and soft tissue resection during spinal surgery. | **Class B** |
| 189 | Spinal shaver system blade | A cutting device designed for use in a powered spinal decompression shaver system handpiece (not included) for bone and soft-tissue resection during spinal surgery. | **Class B** |
| 190 | Spinal shaver system handpiece | A power-driven hand-held device used as a component of a shaver system which is used for the removal of | **Class B** |

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| | | bone/brawn/cartilage during spinal surgery. | |
| 191 | Stereotactic neuronavigation/planning system | Intended to receive and analyse patient magnetic resonance imaging (MRI) images and position landmarks on these images, then register the images by the mean of a three-dimensional (3-D) optical positioning system (frameless stereotactic neuronavigation) to provide real-time relative positioning for the treatment probes and instruments. | **Class B** |
| 192 | Stereotactic radiosurgical system | Intended to deliver a therapeutic radiation dose to an anatomical region from external beams produced from multiple radionuclide sources arranged in a fixed focal point collimated array; typically used to treat brain, neck, breast and spinal tumours. | **Class D** |
| 193 | Subdermal needle electrode | A sterile, multi-purpose electrical conductor inserted beneath the dermal layer of a patient's skin to record/monitor electrical activity (biopotentials) for physiological measurements [typically electroencephalography (EEG), electromyography (EMG), and evoked-potential) and often to provide electrical stimulation. | **Class C** |
| 194 | Surgical optical-tracking spatial marker cranial anchor (Cranial localizer holder for surgical navigation tracking system) | An invasive component of a surgical navigation and/or device tracking system (e.g., optical/electromagnetic device tracking system, computer-assisted neurosurgical ultrasound navigation system, surgical microscope equipped with a tracking camera) intended for intraoperative fixation to a patient's skull to securely receive optical spatial markers/holders. | **Class B** |
| 195 | Tibial nerve percutaneous incontinence-control electrical stimulation system | Intended to treat urinary and/or faecal incontinence with electrical stimuli applied to the sacral nerve via percutaneous tibial nerve stimulation (PTNS). | **Class C** |

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| 196 | Transcranial magnetic stimulation system | An assembly of electrically-powered devices intended for the treatment and/or diagnosis of neurological, psychiatric and/or cognitive conditions (e.g., Alzheimer's disease, major depressive disorder, pain) through noninvasive magnetic stimulation of the brain and/or peripheral nerves. | **Class C** |
| 197 | Transcranial electrical stimulation system, continuous-current and pulsed-current | Intended for one or more psychiatric\neurological therapy types [e.g., transcranial direct current stimulation (tDCS), transcranial alternating current stimulation (tACS)] and to induce a state resembling that of chemically-induced anaesthesia for treating one or more psychiatric disorders which may include anxiety, depression, insomnia, and/or addiction. | **Class C** |
| 198 | Transvenous phrenic nerve electrical stimulation control unit | Intended to configure/deliver stimulation of the phrenic nerve, via a transvenous electrode, to cause contraction of the diaphragm in conjunction with mechanical ventilation to assist earlier ventilation weaning. | **Class D** |
| 199 | Vagus nerve electrical stimulation system programmer | It is intended to program the strength and duration of the electrical impulses for a vagus nerve electrical stimulation system. | **Class C** |
| 200 | Ventricular cerebrospinal fluid drainage catheterization kit | A collection of sterile devices intended for short-term access to the brain ventricles to drain cerebrospinal fluid (CSF) as a means of reducing CSF volume and intracranial pressure (ICP). It includes an intracerebral infusion/drainage catheter and devices intended for catheter insertion (e.g. stylet) and CSF collection (e.g., drip chamber, drainage bag, tubing set). | **Class D** |
| 201 | Ventriculoperitoneal shunt | An implantable device intended to divert excessive cerebrospinal fluid (CSF) from the brain ventricles to the peritoneal cavity, where it can be absorbed into the body, as a treatment for increased intracranial pressure (e.g., caused by hydrocephalus). Disposable devices associated with implantation may be included. | **Class D** |

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| 202 | Ventriculo-peritoneal/atrial shunt | An implantable device intended to divert excessive cerebrospinal fluid (CSF) from the brain ventricles to either the peritoneal cavity or the heart right atrium (i.e., dual-capability), where it can be absorbed into the body, as a treatment for increased intracranial pressure (e.g., caused by hydrocephalus). Disposable devices associated with implantation may be included. | **Class D** |