	Current as of the date July 31, 2018													
Fiscal year of designation (Heisei)	Fiscal year of designation	Date of designation	Designation number	Grant period (years)	Name of the medical device with a designation	Anticipated intended use or indications on the designation	Name of applicant receiving designation	Intended use and indications approved for manufacturing and marketing	Name of applicant obtaining approval for manufacturing and marketing	Date of approval for manufacturing and marketing	Name of product approved for manufacturing and marketing	Notes	Date of revocation of designation	<Status>
5	1993	1993/11/15	(5gu B) No. 1		Implantable defibrillator	Patients at high risk of sudden death due to ventricular tachyarrhythmia	Medtronic Japan Co., Ltd.	Patients at high risk of sudden death from ventricular tachyarrhythmias	Medtronic Japan Co., Ltd.	1994/7/7	PCD 7217 implantable			Approved
5	1993	1993/11/15	(5gu B) No. 2		Adsorption type blood purifier	Patients with advanced dialysis-related amyloidosis (DRA) resulting in significant restrictions in daily life due to severe mobility impairment	Kanegafuchi Chemical Industrial Co., Ltd.	Patients with advanced dialysis-related amyloidosis (DRA) resulting in significant restrictions in daily life due to severe mobility impairment	Kaneka Corporation	1994/4/8	Lixelle			Approved
7	1995	1995/4/1	(7gu A) No. 3	3	Magnetic cell separation system	Separation and isolation of hematopoietic stem cells (CD34-positive cells) during allogeneic or autologous bone marrow transplantation or autologous peripheral blood stem cell transplantation.	Baxter	Separation and isolation of hematopoietic stem cells (CD34-positive cells) during autologous bone marrow or peripheral blood stem cell transplantation in patients with malignant tumors	Takara Bio, Inc.	2001/8/31	Isolex 300	This device is currently not being supplied.		Approved
7	1995	1995/4/1	(7gu A) No. 4	2	Lymphocyte isolation equipment	Elimination of T lymphocytes for allogeneic bone marrow transplantation	Asahi Medical Co., Ltd.	-	-	-	-	Designation revoked (1999/05/27)	1999/5/27	Revoked
8	1996	1996/4/1	(8gu A) No. 5	3	Partially disposable pump system for pain relief	Alleviation of severe pain associated with various types of cancer for which oral administration, intravenous injection or subcutaneous injection of narcotics is not expected to be sufficiently effective	Terumo Corp	-	-	-	-	Designation revoked (2001/08/24)	2001/8/24	Revoked
11	1999	1999/5/27	(11gu) No. 6		Implantable ventricular assist device	Improvement of cardiac function or systemic condition, including prevention or improvement of dysfunction of various organs secondary to heart failure and reduction of the number or dosage of drugs used prior to surgery in patients with end-stage heart failure, including those with acute myocarditis which led to dilated cardiomyopathy, ischemic heart disease, acquired valvular disease or chronic heart failure, and patients with other types of cardiogenic circulatory failure who developed severe heart failure while waiting for heart transplantation or require long-term circulatory support, for whom survival is difficult even with assisted circulation and maximal medical therapy approved in Japan	Nissho Co., Ltd.	Improvement of circulation in patients with severe heart failure with persisting decompensation after failing conventional treatments (drug therapy and existing assisted circulation) for whom survival is difficult without heart transplantation	Nipro Corporation	2009/11/18	HeartMate XVE implantable left ventricular assist system			Approved

Fiscal year of designation (Heisei)	Fiscal year of designation	Date of designation	Designation number	Grant period (years)	Name of the medical device with a designation	Anticipated intended use or indications on the designation	Name of applicant receiving designation	Intended use and indications approved for manufacturing and marketing	Name of applicant obtaining approval for manufacturing and marketing	Date of approval for manufacturing and marketing	Name of product approved for manufacturing and marketing	Notes	Date of revocation of designation	<Status>
11	1999	1999/8/25	(11gu) No. 7		Implantable ventricular assist device	Long-term maintenance of blood circulation, including as a bridge to heart transplantation, for patients with severe irreversible end-stage heart failure at risk of death due to decreased cardiac function	Baxter	Improvement of circulation in patients with severe heart failure with persisting decompensation after failing conventional treatments (drug therapy and existing assisted circulation) for whom survival is difficult without heart transplantation	Edwards Lifesciences Corporation	2001/8/31	Novacor left ventricular assist system	Designation revoked (2013/5/14)	2013/5/14	Approved
12	2000	2000/6/16	(12gu) No. 8	5	Magnetic cell separation system	Separation and isolation of hematopoietic stem cells (CD34-positive cells) during allogeneic bone marrow or peripheral blood stem cell transplantation, autologous bone marrow or peripheral blood stem cell transplantation or umbilical cord blood transplantation for the treatment of malignant tumors, non-neoplastic disease, congenital disease or severe autoimmune disease	Kirin Brewery Company, Limited	-	-	-	-	Designation revoked (2006/12/21)	2006/12/21	Revoked
13	2001	2001/4/23	(13gu) No. 9	3	Adsorption type blood purifier	Induction of remission in patients with active Crohn's disease	Japan Immunoreseach Laboratories Co., LTD	Induction of remission in patients with moderate to severe active Crohn’s disease experiencing clinical symptoms caused by pathological changes in the large intestine where nutritional therapy and existing drug therapies are ineffective or cannot be used	JIMRO Co., Ltd.	2008/9/2	Adacolumn			Approved
13	2001	2001/8/1	(13gu) No. 10		Programmable implantable pump for continuous infusion	Cerebral (infantile) palsy, spinal cord vascular disorders, cervical spondylosis, posterior longitudinal ligament ossification, multiple sclerosis, spinocerebellar degeneration (hereditary spastic paraplegia), or severe spastic paralysis due to traumatic sequelae (spinal cord injury or head trauma)	Medtronic Japan Co., Ltd.	A pump for intrathecal administration of baclofen for intrathecal injection in patients with severe spastic paralysis resulting from cerebrospinal diseases (limited to cases where existing treatments are not sufficiently effective) . This product is intended for adults (17 years or older).	Medtronic Japan Co., Ltd.	2005/3/25	SynchroMed EL pump			Approved
17	2005	2005/10/14	(17ki) No. 11		Purifier for the removal of blood cells	Inhibition of ocular symptoms in patients with Behcet's disease with refractory uveoretinitis	JIMRO Co., Ltd.	-	-	-	-			

Fiscal year of designation (Heisei)	Fiscal year of designation	Date of designation	Designation number	Grant period (years)	Name of the medical device with a designation	Anticipated intended use or indications on the designation	Name of applicant receiving designation	Intended use and indications approved for manufacturing and marketing	Name of applicant obtaining approval for manufacturing and marketing	Date of approval for manufacturing and marketing	Name of product approved for manufacturing and marketing	Notes	Date of revocation of designation	<Status>
17	2005	2005/12/9	(17ki) No. 12		Prosthesis promoting intravascular embolization in the central circulation	Prevention of protrusion and derailment of a coil mass into the parent artery during coil embolization surgery for patients with wide-neck cerebral aneurysms (neck width ≥ 4 mm or dome-to-neck ratio < 2) among those with unruptured cerebral aneurysms (maximum diameter ≥10 mm) that are difficult to treat with surgical intervention (e.g. clipping) or with coil embolic therapy using embolic coils alone	Johnson & Johnson K.K.	Prevention of protrusion and derailment of a coil mass into the parent artery during coil embolization surgery for patients with unruptured cerebral aneurysms of ≥7 mm in maximum diameter on parent arteries of 2.5 to 4 mm in diameter among those with wide-neck cerebral aneurysms (neck width ≥ 4 mm or dome-to-neck ratio < 2) that are difficult to treat with surgical intervention (e.g. clipping) or with coil embolic therapy using embolic coils alone	Johnson & Johnson K.K.	2010/1/8	Codman Enterprise vascular reconstruction device (VRD)			Approved
19	2007	2007/7/6	(19ki) No. 13	2	Implantable ventricular assist system	Improvement and maintenance of blood circulation in patients with irreversible end-stage heart failure with dilated cardiomyopathy or ischemic heart disease for whom heart transplantation is indicated and who have no chance of recovery with conventional medical therapies (drug therapy or intra-aortic balloon pump for assisted circulation) at imminent risk of death due to decreased cardiac function	Sun Medical Technology Research Corp.	Improvement of circulation for the period prior to heart transplantation in patients with severe heart failure for which heart transplantation is indicated and who have persisting decompensation despite drug therapy or circulatory assist devices such as an external ventricular assist device and for whom survival is difficult without heart transplantation	Sun Medical Technology Research Corp.	2010/12/8	Evaheart left ventricular assist system			Approved
20	2008	2008/6/11	(20ki) No. 14		Prosthesis promoting intravascular embolization in the central circulation	Prevention of protrusion and derailment of a coil mass into the parent artery during coil embolization surgery for patients with wide-neck cerebral aneurysms (neck width ≥ 4 mm or dome-to-neck ratio < 2) among those with unruptured cerebral aneurysms (maximum diameter ≥10 mm) that are difficult to treat with surgical intervention (e.g. clipping) or with coil embolic therapy using embolic coils alone	Boston Scientific Corporation	-	-	-	-	Designation revoked (2011/12/09)	2011/12/9	Revoked
(20ki) No. 15 is regarded as orphan products for regenerative medicine. .														

Fiscal year of designation (Heisei)	Fiscal year of designation	Date of designation	Designation number	Grant period (years)	Name of the medical device with a designation	Anticipated intended use or indications on the designation	Name of applicant receiving designation	Intended use and indications approved for manufacturing and marketing	Name of applicant obtaining approval for manufacturing and marketing	Date of approval for manufacturing and marketing	Name of product approved for manufacturing and marketing	Notes	Date of revocation of designation	<Status>
20	2008	2008/12/15	(20ki) No. 16	1	Semiconductor laser for photodynamic therapy (PDT)	Used in combination with the light-sensitive substance talaporfin sodium for the treatment of malignant glioma	Panasonic Shikoku Electronics Co., Ltd. (Currently, Panasonic Healthcare Co., Ltd.)	-	-	-	-	Designation revoked (2013/09/19) Designation was transferred to (25ki) No. 24 with a change in the anticipated intended use or indication from malignant glioma to malignant brain tumor (expansion	2013/9/19	Revoked
20	2008	2008/12/15	(20ki) No. 17	2	Implantable ventricular assist system	Used as a bridge to heart transplantation in patients with end-stage severe heart failure who meet the criteria for heart transplantation and who are at imminent risk of death due to decreased cardiac function	Century Medical, Inc.	Improvement of circulation for the period prior to heart transplantation in patients with severe heart failure for which heart transplantation is indicated and who have persisting decompensation despite drug therapy or circulatory assist devices such as an external ventricular assist device and for whom survival is difficult unless without heart transplantation	Century Medical, Inc.	2013/11/22	Jarvik2000 Implantable ventricular assist system			Approved
20	2008	2009/3/11	(21ki) No. 18		Implantable ventricular assist system	Improvement of circulation in patients with end-stage heart failure who require heart transplantation.	Terumo Corp	Improvement of circulation for the period prior to heart transplantation in patients with severe heart failure for which heart transplantation is indicated and who have persisting decompensation despite drug therapy or circulatory assist devices such as an external ventricular assist device and for whom survival is difficult unless without heart transplantation	Terumo Corporation	2010/12/8	DuraHeart left ventricular assist system			Approved

Fiscal year of designation (Heisei)	Fiscal year of designation	Date of designation	Designation number	Grant period (years)	Name of the medical device with a designation	Anticipated intended use or indications on the designation	Name of applicant receiving designation	Intended use and indications approved for manufacturing and marketing	Name of applicant obtaining approval for manufacturing and marketing	Date of approval for manufacturing and marketing	Name of product approved for manufacturing and marketing	Notes	Date of revocation of designation	<Status>
21	2009	2009/7/7	(21ki) No. 19	3	Purifier for the removal of blood cells	Improvement of clinical symptoms in patients with pustular psoriasis	JIMRO Co., Ltd.	Used for improvement of clinical symptoms of moderate or severe pustular psoriasis for which existing oral therapies are ineffective or cannot be used in systemic treatment	JIMRO Co., Ltd.	2012/6/25	Adacolumn			Approved
21	2009	2009/10/28	(21ki) No. 20	3	Endobronchial loading material	Treatment of secondary refractory pneumothorax or bronchial fistula where surgery is difficult	Harada Corporation	Loading into bronchi for the purpose of closing a fistula in patients with secondary refractory pneumothorax, air leak persisting after pneumonectomy or other fistulae which are difficult to treat with surgery and for whom bronchial occlusion is indicated	Harada Corporation	2013/1/28	Endobronchial Watanabe Spigot (EWS)			Approved
21	2009	2010/3/19	(22ki) No. 21	1	Fetal shunt	Placement into the fetal chest cavity and the maternal amniotic fluid cavity in order to continuously drain the pleural effusion accumulating in the fetal thoracic cavity into the amniotic sac, thereby improving hydrops fetalis, preventing pulmonary hypoplasia and prolonging pregnancy	Hakko Co., Ltd.	Continuous drainage of pleural effusion into amniotic fluid cavity in cases of fetal pleural effusion when thoracocentesis has failed	Hakko Co., Ltd.	2011/12/20	Fetal shunt			Approved
(23ki) No. 22 is regarded as orphan products for regenerative medicine.														
23	2011	2011/6/17	(23ki) No. 23	3	Pump for external ventricular assist device	Improvement of circulation before heart transplantation or restoration of cardiac function in pediatric patients (with body surface area ≤1.5 m² and body weight between 2 kg and 60 kg) with severe heart failure whose symptoms do not improve with conventional medication or assisted circulation	Cardio, Inc.	This product will be used for severe pediatric heart failure patients who never anticipate a recovery by the conventional treatments, surgical operations and assisted. This product will be used only for appropriate pediatric patients as BTT and BTR.	Cardio, Inc.	2015/6/18	EXCOR Pediatric ventricular assist device			Approved
25	2013	2013/9/19	(25ki) No. 24	1	Semiconductor laser for photodynamic therapy (PDT)	Use in combination with the light-sensitive substance talaporfin sodium for the treatment of malignant brain tumors	Panasonic Healthcare Co., Ltd.	Use in photodynamic therapy (PDT) with the light-sensitive substance talaporfin sodium Target disease: primary malignant brain tumors (limited to cases treated with surgical resection)	Panasonic Healthcare Co., Ltd.	2013/9/20	PD Laser BT	Designation was transferred from (20ki) No. 16 with the change in anticipated intended use or indication from malignant glioma to malignant brain tumor		Approved

Fiscal year of designation (Heisei)	Fiscal year of designation	Date of designation	Designation number	Grant period (years)	Name of the medical device with a designation	Anticipated intended use or indications on the designation	Name of applicant receiving designation	Intended use and indications approved for manufacturing and marketing	Name of applicant obtaining approval for manufacturing and marketing	Date of approval for manufacturing and marketing	Name of product approved for manufacturing and marketing	Notes	Date of revocation of designation	<Status>
26	2014	2014/9/17	(26ki) No. 25		Semiconductor laser for photodynamic therapy (PDT)	Local failure after chemoradiotherapy or radiotherapy for esophageal cancer	Panasonic Healthcare Co., Ltd.	Local failure after chemoradiotherapy or radiotherapy for esophageal cancer	Meiji Seika Pharma Co., Ltd.	2015/5/26	PD Laser EC-PDT			Approved
26	2014	2014/12/19	(26ki) No. 26		HAl for medical use (lower limb type)	Inhibition of progression of muscular atrophy and muscle weakness, in patients with indolent or chronic progressive neuromuscular intractable diseases , by supporting for muscle contraction after wearing the HAL on a regular and intermittent basis	CYBERDYNE Inc	HAL is used to improve gait function in patients with slowly progressive neuromuscular disease. HAL improves gait function by assisting the movement of lower limbs according to bio-electric signals during gait training. Patients wear HAL intermittently to repeat the training.	CYBERDYNE Inc	2015/11/25	HAL®for Medical Use - Lower Limb Model			Approved
26	2014	2014/12/19	(26ki) No. 27		Tear exchangeable limbal supported rigid contact lens	Correction of visual acuity and improvement of symptoms in patients with ocular sequelae caused by erythema exsudativum multiforme major （stevens-Johnson syndrome, toxic epidermal necrolysis)	SUN CONTACT LENS Co., Ltd.	-	-	-	-			
28	2016	2016/9/2	(28ki)No. 28	2	Titanium Bridge	improvement in symptoms of adductor spasmodic dysphonia	Nobelpharma Co., Ltd.	improvement in symptoms of adductor spasmodic dysphonia	Nobelpharma Co., Ltd.	2017/12/15	TITANBRIDGE	sakigake(27ki)No.1		Approved
29	2017	2017/7/10	(29ki)No. 29		Extracorporeal Photopheresis System	This system is used in the extracorporeal photopheresis therapy for Steroid-refractory and intolerance chronic graft-versus-host disease.	Vorpal Technologies K.K.	-	-	-	(USA:THERAKOSTM CELLEX® Photopheresis System)			