Provisional Translation (as of August 2025).
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User fees for reviews, etc. of medical devices and in vitro diagnostics based on the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145, 1960)

Note) The applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics are shown in the lower rows in the field of user fees. (unit: yen)

Category				User fees		
				Review	Conformity	Total
Review for approval of medical devices/in vitro diagnostics (new approval)						
New medical devices (Class IV)				16,431,300	1,289,900 (+ overseas travel expenses *1)	17,721,200 (+ overseas travel expenses *1)
				Article 33, Paragraph 1, Item 1 (a) (1)	Article 33, Paragraph 2, Item 1 (a)	
	Without clinical data			Same as above	89,400 (*2) (+ overseas travel expenses *1)	16,520,700 (+ overseas travel expenses *1)
					Article 33, Paragraph 2, Item 1 (c)	
New medical devices (Class II/III)				11,727,000	1,289,900 (+ overseas travel expenses *1)	13,016,900 (+ overseas travel expenses *1)
				Article 33, Paragraph 1, Item 1 (a) (3)	Article 33, Paragraph 2, Item 1 (a)	
	Without clinical data			Same as above	89,400 (*2) (+ overseas travel expenses *1)	11,816,400 (+ overseas travel expenses *1)
					Article 33, Paragraph 2, Item 1 (c)	
Improved medical devices/with clinical data (Class IV)				9,381,400	1,032,000 (+ overseas travel expenses *1)	10,413,400 (+ overseas travel expenses *1)
				Article 33, Paragraph 1, Item 1 (a) (2)	Article 33, Paragraph 2, Item 1 (b)	
	Without clinical data			Same as above	89,400 (*2) (+ overseas travel expenses *1)	9,470,800 (+ overseas travel expenses *1)
					Article 33, Paragraph 2, Item 1 (c)	
Improved medical devices/with clinical data (Class II/III)				5,618,800	1,032,000 (+ overseas travel expenses *1)	6,650,800 (+ overseas travel expenses *1)
				Article 33, Paragraph 1, Item 1 (a) (4)	Article 33, Paragraph 2, Item 1 (b)	
	Without clinical data			Same as above	89,400 (*2) (+ overseas travel expenses *1)	5,708,200 (+ overseas travel expenses *1)
					Article 33, Paragraph 2, Item 1 (c)	
Improved medical devices/without clinical data/without approval standards (Class IV)				2,991,200	89,400 (*2) (+ overseas travel expenses *1)	3,080,600 (+ overseas travel expenses *1)
				Article 33, Paragraph 1, Item 1 (a) (7)	Article 33, Paragraph 2, Item 1 (c)	
Generic medical devices/without clinical data/without approval standards (Class IV)				2,244,900	89,400 (*2) (+ overseas travel expenses *1)	2,334,300 (+ overseas travel expenses *1)
				Article 33, Paragraph 1, Item 1 (a) (8)	Article 33, Paragraph 2, Item 1 (c)	
Improved generic medical devices/without clinical data/without approval standards (Class II/III)				1,790,500	89,400 (*2) (+ overseas travel expenses *1)	1,879,900 (+ overseas travel expenses *1)
				Article 33, Paragraph 1, Item 1 (a) (9)	Article 33, Paragraph 2, Item 1 (c)	
Generic medical devices/with approval standards (Class IV)				545,000	89,400 (*2) (+ overseas travel expenses *1)	634,400 (+ overseas travel expenses *1)
				Article 33, Paragraph 1, Item 1 (a) (5)	Article 33, Paragraph 2, Item 1 (c)	
Generic medical devices/with approval standards (Class II/III)				437,000	89,400 (*2) (+ overseas travel expenses *1)	526,400 (+ overseas travel expenses *1)
				Article 33, Paragraph 1, Item 1 (a) (6)	Article 33, Paragraph 2, Item 1 (c)	
Re-manufactured single-use medical devices	(Class IV)			9,381,400	1,032,000 (+ overseas travel expenses *1)	10,413,400 (+ overseas travel expenses *1)
				Article 33, Paragraph 1, Item 1 (a) (2)	Article 33, Paragraph 2, Item 1 (b)	
	(Class II/III)			5,618,800	1,032,000 (+ overseas travel expenses *1)	6,650,800 (+ overseas travel expenses *1)
				Article 33, Paragraph 1, Item 1 (a) (4)	Article 33, Paragraph 2, Item 1 (b)	
In vitro diagnostics	New products	Excluding companion diagnostics		2,534,000		2,534,000
				Article 33, Paragraph 1, Item 1 (b) (2)		
		Companion diagnostics		4,295,000		4,295,000
				Article 33, Paragraph 1, Item 1 (b) (3)		
	Outside the scope of approval standards	With clinical data	Excluding companion diagnostics	2,534,000		2,534,000
				Article 33, Paragraph 1, Item 1 (b) (2)		
			Companion diagnostics	4,295,000		4,295,000
				Article 33, Paragraph 1, Item 1 (b) (3)		
		Without clinical data		2,362,200		2,362,200
				Article 33, Paragraph 1, Item 1 (b) (4)		
	Nonconformity with approval standards	With clinical data	Excluding companion diagnostics	2,534,000		2,534,000
				Article 33, Paragraph 1, Item 1 (b) (2)		
			Companion diagnostics	4,295,000		4,295,000
				Article 33, Paragraph 1, Item 1 (b) (3)		
		Without clinical data		1,318,600		1,318,600
				Article 33, Paragraph 1, Item 1 (b) (6)		
	Conformity with approval standards	Without clinical data		454,800		454,800
				Article 33, Paragraph 1, Item 1 (b) (5)		
	Addition of series			63,300		63,300
				Article 33, Paragraph 1, Item 1 (b) (1)		
Addition of brand name				37,300		37,300
				Article 33, Paragraph 1, Item 1 (c)		

(*1) Amount including overseas travel expenses in cases where the inspection is conducted in a foreign country (Article 33, Paragraph 3)

(*2) No user fees are required for application for approval of a new product with status similar to succession ("Handling of approvals for manufacturing, import, and foreign manufacturing of drugs, etc." PAB Notification No. 821; September 21, 1987).

Note) The applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices are shown in the lower rows in the field of user fees. (unit: yen)

Category				User fees		
				Review	Conformity	Total
Review for approval of medical devices/in vitro diagnostics (approval for partial changes to approved matters)						
New medical devices (Class IV)				8,224,300 Article 33, Paragraph 1, Item 2 (a) (1)	1,289,900 (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (a)	9,514,200 (+ overseas travel expenses *1)
	Without clinical data			Same as above	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	8,272,700 (+ overseas travel expenses *1)
New medical devices (Class II/III)				5,869,700 Article 33, Paragraph 1, Item 2 (a) (3)	1,289,900 (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (a)	7,159,600 (+ overseas travel expenses *1)
	Without clinical data			Same as above	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	5,918,100 (+ overseas travel expenses *1)
Improved medical devices/with clinical data (Class IV)				4,695,800 Article 33, Paragraph 1, Item 2 (a) (2)	1,032,000 (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (b)	5,727,800 (+ overseas travel expenses *1)
	Without clinical data			Same as above	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	4,744,200 (+ overseas travel expenses *1)
Improved medical devices/with clinical data (Class II/III)				2,827,300 Article 33, Paragraph 1, Item 2 (a) (4)	1,032,000 (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (b)	3,859,300 (+ overseas travel expenses *1)
	Without clinical data			Same as above	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	2,875,700 (+ overseas travel expenses *1)
Improved medical devices/without clinical data/without approval standards (Class IV)				1,500,100 Article 33, Paragraph 1, Item 2 (a) (7)	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	1,548,500 (+ overseas travel expenses *1)
Generic medical devices/without clinical data/without approval standards (Class IV)				1,122,900 Article 33, Paragraph 1, Item 2 (a) (8)	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	1,171,300 (+ overseas travel expenses *1)
Improved generic medical devices/without clinical data/without approval standards (Class II/III)				901,100 Article 33, Paragraph 1, Item 2 (a) (9)	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	949,500 (+ overseas travel expenses *1)
Generic medical devices/with approval standards (Class IV)				276,300 Article 33, Paragraph 1, Item 2 (a) (5)	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	324,700 (+ overseas travel expenses *1)
Generic medical devices/with approval standards (Class II/III)				220,400 Article 33, Paragraph 1, Item 2 (a) (6)	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	268,800 (+ overseas travel expenses *1)
Others (medical devices)				182,200 Article 33, Paragraph 1, Item 2 (a) (10)	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	230,600 (+ overseas travel expenses *1)
	Without inspection			Same as above		182,200
Re-manufactured single-use medical devices	With re-manufacturing design and manufacturing data	(Class IV)		4,695,800 Article 33, Paragraph 1, Item 2 (a) (2)	1,032,000 (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (b)	5,727,800 (+ overseas travel expenses *1)
			Without study data on design/manufacturing	Same as above	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	4,744,200 (+ overseas travel expenses *1)
		(Class II/III)		2,827,300 Article 33, Paragraph 1, Item 2 (a) (4)	1,032,000 (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (b)	3,859,300 (+ overseas travel expenses *1)
			Without study data on design/manufacturing	Same as above	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	2,875,700 (+ overseas travel expenses *1)
	Without re-manufacturing design or manufacturing data	(Class IV)		1,122,900 Article 33, Paragraph 1, Item 2 (a) (8)	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	1,171,300 (+ overseas travel expenses *1)
		(Class II/III)		901,100 Article 33, Paragraph 1, Item 2 (a) (9)	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	949,500 (+ overseas travel expenses *1)
	Others			182,200 Article 33, Paragraph 1, Item 2 (a) (10)	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	230,600 (+ overseas travel expenses *1)
In vitro diagnostics	Outside the scope of approval standards	With clinical data	Excluding companion diagnostics	1,048,200 Article 33, Paragraph 1, Item 2 (b) (2)		1,048,200
			Companion diagnostics	1,996,600 Article 33, Paragraph 1, Item 2 (b) (3)		1,996,600
		Without clinical data	Excluding companion diagnostics	295,600 Article 33, Paragraph 1, Item 2 (b) (4)		295,600
			Companion diagnostics	1,007,200 Article 33, Paragraph 1, Item 2 (b) (5)		1,007,200
	Nonconformity with approval standards	With clinical data	Excluding companion diagnostics	1,048,200 Article 33, Paragraph 1, Item 2 (b) (2)		1,048,200
			Companion diagnostics	1,996,600 Article 33, Paragraph 1, Item 2 (b) (3)		1,996,600
		Without clinical data	Excluding companion diagnostics	295,600 Article 33, Paragraph 1, Item 2 (b) (4)		295,600
			Companion diagnostics	1,007,200 Article 33, Paragraph 1, Item 2 (b) (5)		1,007,200
	Conformity with approval standards	Without clinical data		295,600 Article 33, Paragraph 1, Item 2 (b) (6)		295,600
	Addition of series			33,400 Article 33, Paragraph 1, Item 2 (b) (1)		33,400
Others (in vitro diagnostics)				150,600 Article 33, Paragraph 1, Item 2 (b) (7)		150,600

(*1) Amount including overseas travel expenses in cases where the inspection is conducted in a foreign country (Article 33, Paragraph 3)

(*2) No user fees are required if there are no data subject to integrity assessment, i.e., application for approval for partial changes to approved matters for addition or deletion of manufacturing site (new application for change or replacement of brand name).

Note) The applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices are shown in the lower rows in the field of user fees. (unit: yen)

Category		User fees		
		Review	Conformity	Total
Review for approval of medical devices (emergency approval)				
At the time of application	New medical devices (Class IV)	16,431,300	970,100 (+ overseas travel expenses *1)	17,401,400 (+ overseas travel expenses *1)
		Article 33, Paragraph 1, Item 1 (a) (1)	Article 33, Paragraph 2, Item 3	
	New medical devices (Class II/III)	11,727,000	970,100 (+ overseas travel expenses *1)	12,697,100 (+ overseas travel expenses *1)
		Article 33, Paragraph 1, Item 1 (a) (3)	Article 33, Paragraph 2, Item 3	
	Improved medical devices/with clinical data (Class IV)	9,381,400	970,100 (+ overseas travel expenses *1)	10,351,500 (+ overseas travel expenses *1)
		Article 33, Paragraph 1, Item 1 (a) (2)	Article 33, Paragraph 2, Item 3	
	Improved medical devices/with clinical data (Class II/III)	5,618,800	970,100 (+ overseas travel expenses *1)	6,588,900 (+ overseas travel expenses *1)
		Article 33, Paragraph 1, Item 1 (a) (4)	Article 33, Paragraph 2, Item 3	
	Improved medical devices/without clinical data/without approval standards (Class IV)	2,991,200	970,100 (+ overseas travel expenses *1)	3,961,300 (+ overseas travel expenses *1)
		Article 33, Paragraph 1, Item 1 (a) (7)	Article 33, Paragraph 2, Item 3	
	Improved medical devices/without clinical data/without approval standards (Class II/III)	1,790,500	970,100 (+ overseas travel expenses *1)	2,760,600 (+ overseas travel expenses *1)
		Article 33, Paragraph 1, Item 1 (a) (9)	Article 33, Paragraph 2, Item 3	
At the time of application for change	New medical devices (Class IV)	8,224,300	970,100 (+ overseas travel expenses *1)	9,194,400 (+ overseas travel expenses *1)
		Article 33, Paragraph 1, Item 2 (a) (1)	Article 33, Paragraph 2, Item 3	
	New medical devices (Class II/III)	5,869,700	970,100 (+ overseas travel expenses *1)	6,839,800 (+ overseas travel expenses *1)
		Article 33, Paragraph 1, Item 2 (a) (3)	Article 33, Paragraph 2, Item 3	
	Improved medical devices/with clinical data (Class IV)	4,695,800	970,100 (+ overseas travel expenses *1)	5,665,900 (+ overseas travel expenses *1)
		Article 33, Paragraph 1, Item 2 (a) (2)	Article 33, Paragraph 2, Item 3	
	Improved medical devices/with clinical data (Class II/III)	2,827,300	970,100 (+ overseas travel expenses *1)	3,797,400 (+ overseas travel expenses *1)
		Article 33, Paragraph 1, Item 2 (a) (4)	Article 33, Paragraph 2, Item 3	
	Improved medical devices/without clinical data/without approval standards (Class IV)	1,500,100	970,100 (+ overseas travel expenses *1)	2,470,200 (+ overseas travel expenses *1)
		Article 33, Paragraph 1, Item 2 (a) (7)	Article 33, Paragraph 2, Item 3	
	Improved generic medical devices/without clinical data/without approval standards (Class II/III)	901,100	970,100 (+ overseas travel expenses *1)	1,871,200 (+ overseas travel expenses *1)
		Article 33, Paragraph 1, Item 2 (a) (9)	Article 33, Paragraph 2, Item 3	

(*1) Amount including overseas travel expenses in cases where the inspection is conducted in a foreign country (Article 33, Paragraph 3)

Note) The applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices are shown in the lower rows in the field of user fees. (unit: yen)

Category				User fees		
				Review	Conformity	Total
Review of plan to change approved information on medical devices/in vitro diagnostics						
New medical devices (Class IV)				8,224,300		8,224,300
				Article 34-2, Paragraph 1, Item 1 (a)		
New medical devices (Class II/III)				5,869,700		5,869,700
				Article 34-2, Paragraph 1, Item 1 (c)		
Improved medical devices/with clinical data (Class IV)				4,695,800		4,695,800
				Article 34-2, Paragraph 1, Item 1 (b)		
Improved medical devices/with clinical data (Class II/III)				2,827,300		2,827,300
				Article 34-2, Paragraph 1, Item 1 (d)		
Improved medical devices/without clinical data/without approval standards (Class IV)				1,500,100		1,500,100
				Article 34-2, Paragraph 1, Item 1 (g)		
Generic medical devices/without clinical data/without approval standards (Class IV)				1,122,900		1,122,900
				Article 34-2, Paragraph 1, Item 1 (h)		
Improved generic medical devices/without clinical data/without approval standards (Class II/III)				901,100		901,100
				Article 34-2, Paragraph 1, Item 1 (i)		
Generic medical devices/with approval standards (Class IV)				276,300		276,300
				Article 34-2, Paragraph 1, Item 1 (e)		
Generic medical devices/with approval standards (Class II/III)				220,400		220,400
				Article 34-2, Paragraph 1, Item 1 (f)		
Others (medical devices)				182,200		182,200
				Article 34-2, Paragraph 1, Item 2		
In vitro diagnostics	Outside the scope of approval standards	With clinical data	Excluding companion diagnostics	1,048,200		1,048,200
				Article 34-2, Paragraph 1, Item 3 (c)		
			Companion diagnostics	1,996,600		1,996,600
				Article 34-2, Paragraph 1, Item 3 (b)		
		Without clinical data	Excluding companion diagnostics	295,600		295,600
				Article 34-2, Paragraph 1, Item 3 (e)		
			Companion diagnostics	1,007,200		1,007,200
				Article 34-2, Paragraph 1, Item 3 (d)		
	Nonconformity with approval standards	With clinical data	Excluding companion diagnostics	1,048,200		1,048,200
				Article 34-2, Paragraph 1, Item 3 (c)		
			Companion diagnostics	1,996,600		1,996,600
				Article 34-2, Paragraph 1, Item 3 (b)		
		Without clinical data	Excluding companion diagnostics	295,600		295,600
				Article 34-2, Paragraph 1, Item 3 (e)		
			Companion diagnostics	1,007,200		1,007,200
				Article 34-2, Paragraph 1, Item 3 (d)		
	Conformity with approval standards	Without clinical data		295,600		295,600
				Article 34-2, Paragraph 1, Item 3 (f)		
	Addition of series			33,400		33,400
				Article 34-2, Paragraph 1, Item 3 (a)		
Others (in vitro diagnostics)				150,600		150,600
				Article 34-2, Paragraph 1, Item 4		

Note) The applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices are shown in the lower rows in the field of user fees. (unit: yen)

Category					User fees		
					Review	Conformity	Total
QMS inspection of medical devices/in vitro diagnostics							
Fee paid by MAH	Issuance fee for certification of conformity with approval standards					50,400	50,400
						Article 33, Paragraph 5, Item 1 (a), Item 2 (a), Item 3 (a) and Paragraph 6, Item 1 (a), Item 2 (a), Item 3 (a); Article 34-2, Paragraph 2, Item 1 and Paragraph 3, Item 1	
	New application	New medical devices				386,600	386,600
						Article 33, Paragraph 5, Item 1 (a) (2)	
			Manufacturing authorization holders for Class II medical devices			386,600	386,600
						Article 33, Paragraph 6, Item 1 (a) (2)	
		Class IV				374,500	374,500
						Article 33, Paragraph 5, Item 1 (a) (3)	
		Biological drugs				398,500	398,500
						Article 33, Paragraph 5, Item 1 (a) (1)	
			Manufacturing authorization holders for Class II medical devices			398,500	398,500
						Article 33, Paragraph 6, Item 1 (a) (1)	
		Other medical devices				374,500	374,500
						Article 33, Paragraph 5, Item 1 (a) (4)	
			Manufacturing authorization holders for Class II medical devices			262,100	262,100
						Article 33, Paragraph 6, Item 1 (a) (3)	
		In vitro diagnostics				272,900	272,900
						Article 33, Paragraph 5, Item 1 (a) (5)	
	Partial change	Class IV				134,000	134,000
						Article 33, Paragraph 5, Item 2 (a) (2)	
		Biological drugs				145,600	145,600
						Article 33, Paragraph 5, Item 2 (a) (1)	
			Manufacturing authorization holders for Class II medical devices			145,600	145,600
						Article 33, Paragraph 6, Item 2 (a) (1)	
		Other medical devices				127,800	127,800
						Article 33, Paragraph 5, Item 2 (a) (3)	
			Manufacturing authorization holders for Class II medical devices			89,400	89,400
						Article 33, Paragraph 6, Item 2 (a) (2)	
		In vitro diagnostics				93,200	93,200
						Article 33, Paragraph 5, Item 2 (a) (4)	
	Review of plan to change	Class IV				134,000	134,000
						Article 34-2, Paragraph 2, Item 1 (b)	
		Biological drugs				145,600	145,600
						Article 34-2, Paragraph 2, Item 1 (a)	
			Manufacturing authorization holders for Class II medical devices			145,600	145,600
						Article 34-2, Paragraph 3, Item 1 (a)	
		Other medical devices				127,800	127,800
						Article 34-2, Paragraph 2, Item 1 (c)	
			Manufacturing authorization holders for Class II medical devices			89,400	89,400
						Article 34-2, Paragraph 3, Item 1 (b)	
		In vitro diagnostics				93,200	93,200
						Article 34-2, Paragraph 2, Item 1 (d)	
	Renewal	Class IV				167,600	167,600
						Article 33, Paragraph 5, Item 3 (a) (2)	
		Biological drugs				176,900	176,900
						Article 33, Paragraph 5, Item 3 (a) (1)	
			Manufacturing authorization holders for Class II medical devices			176,900	176,900
						Article 33, Paragraph 6, Item 3 (a) (1)	
		Other medical devices				149,200	149,200
						Article 33, Paragraph 5, Item 3 (a) (3)	
			Manufacturing authorization holders for Class II medical devices			104,400	104,400
						Article 33, Paragraph 6, Item 3 (a) (2)	
		In vitro diagnostics				129,700	129,700
						Article 33, Paragraph 5, Item 3 (a) (4)	

Note) The applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices are shown in the lower rows in the field of user fees.

(unit: yen)

Category			User fees		
			Review	Conformity	Total
QMS inspection of medical devices/in vitro diagnostics					
New application	Design			86,100	86,100
				Article 33, Paragraph 5, Item 1 (b) (1) and Paragraph 11, Item 1 (a)	
		Manufacturing authorization holders for Class II medical devices		60,200	60,200
				Article 33, Paragraph 6, Item 1 (b) (1)	
	Sterilisation			91,200	91,200
				Article 33, Paragraph 5, Item 1 (b) (3) and Paragraph 11, Item 1 (c)	
		Manufacturing authorization holders for Class II medical devices		63,800	63,800
				Article 33, Paragraph 6, Item 1 (b) (3)	
	Assembly, cleaning, etc.			104,100	104,100
				Article 33, Paragraph 5, Item 1 (b) (2) and Paragraph 11, Item 1 (b)	
		Manufacturing authorization holders for Class II medical devices		72,800	72,800
				Article 33, Paragraph 6, Item 1 (b) (2)	
	Others			90,500	90,500
				Article 33, Paragraph 5, Item 1 (b) (4) and Paragraph 11, Item 1 (d)	
		Manufacturing authorization holders for Class II medical devices		63,200	63,200
				Article 33, Paragraph 6, Item 1 (b) (4)	
	Unregistered			87,500	87,500
				Article 33, Paragraph 5, Item 1 (b) (5); Paragraph 11, Item 1 (e); Paragraph 12, Item 1	
		Manufacturing authorization holders for Class II medical devices		61,200	61,200
				Article 33, Paragraph 6, Item 1 (b) (5)	
Partial change	Design			64,400	64,400
				Article 33, Paragraph 5, Item 2 (b) (1)	
		Manufacturing authorization holders for Class II medical devices		45,000	45,000
				Article 33, Paragraph 6, Item 2 (b) (1)	
	Sterilisation			75,900	75,900
				Article 33, Paragraph 5, Item 2 (b) (3)	
		Manufacturing authorization holders for Class II medical devices		53,100	53,100
				Article 33, Paragraph 6, Item 2 (b) (3)	
	Assembly, cleaning, etc.			87,700	87,700
				Article 33, Paragraph 5, Item 2 (b) (2)	
		Manufacturing authorization holders for Class II medical devices		61,300	61,300
				Article 33, Paragraph 6, Item 2 (b) (2)	
	Others			75,800	75,800
				Article 33, Paragraph 5, Item 2 (b) (4)	
		Manufacturing authorization holders for Class II medical devices		53,000	53,000
				Article 33, Paragraph 6, Item 2 (b) (4)	
	Unregistered			75,900	75,900
				Article 33, Paragraph 5, Item 2 (b) (3)	
		Manufacturing authorization holders for Class II medical devices		53,100	53,100
				Article 33, Paragraph 6, Item 2 (b) (3)	
Review of plan to change	Design			64,400	64,400
				Article 34-2, Paragraph 2, Item 2 (a)	
		Manufacturing authorization holders for Class II medical devices		45,000	45,000
				Article 34-2, Paragraph 3, Item 2 (a)	
	Sterilisation			75,900	75,900
				Article 34-2, Paragraph 2, Item 2 (c)	
		Manufacturing authorization holders for Class II medical devices		53,100	53,100
				Article 34-2, Paragraph 3, Item 2 (c)	
	Assembly, cleaning, etc.			87,700	87,700
				Article 34-2, Paragraph 2, Item 2 (b)	
		Manufacturing authorization holders for Class II medical devices		61,300	61,300
				Article 34-2, Paragraph 3, Item 2 (b)	
	Others			75,800	75,800
				Article 34-2, Paragraph 2, Item 2 (d)	
		Manufacturing authorization holders for Class II medical devices		53,000	53,000
				Article 34-2, Paragraph 3, Item 2 (d)	
	Unregistered			75,900	75,900
				Article 34-2, Paragraph 2, Item 2 (e)	
		Manufacturing authorization holders for Class II medical devices		53,100	53,100
				Article 34-2, Paragraph 3, Item 2 (e)	

Note) The applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices are shown in the lower rows in the field of user fees. (unit: yen)

Category			User fees		
			Review	Conformity	Total
QMS inspection of medical devices/in vitro diagnostics					
Renewal	Design			68,800	68,800
				Article 33, Paragraph 5, Item 3 (b) (1) and Paragraph 11, Item 2 (a)	
		Manufacturing authorization holders for Class II medical devices		48,100	48,100
				Article 33, Paragraph 6, Item 3 (b) (1)	
	Sterilisation			80,100	80,100
				Article 33, Paragraph 5, Item 3 (b) (3) and Paragraph 11, Item 2 (c)	
		Manufacturing authorization holders for Class II medical devices		56,000	56,000
				Article 33, Paragraph 6, Item 3 (b) (3)	
	Assembly, cleaning, etc.			97,400	97,400
				Article 33, Paragraph 5, Item 3 (b) (2) and Paragraph 11, Item 2 (b)	
		Manufacturing authorization holders for Class II medical devices		68,100	68,100
				Article 33, Paragraph 6, Item 3 (b) (2)	
	Others			79,600	79,600
				Article 33, Paragraph 5, Item 3 (b) (4) and Paragraph 11, Item 2 (d)	
		Manufacturing authorization holders for Class II medical devices		55,700	55,700
				Article 33, Paragraph 6, Item 3 (b) (4)	
	Unregistered			76,100	76,100
				Article 33, Paragraph 5, Item 3 (b) (5); Paragraph 11, Item 2 (e); Paragraph 12, Item 2	
		Manufacturing authorization holders for Class II medical devices		53,200	53,200
				Article 33, Paragraph 6, Item 3 (b) (5)	
Options	Micro			47,500	47,500
				Article 33, Paragraph 7, Item 1; Article 34-2, Paragraph 4, Item 1	
		Manufacturing authorization holders for Class II medical devices		33,200	33,200
				Article 33, Paragraph 8; Article 34-2, Paragraph 5	
	Nanomaterial			47,500	47,500
				Article 33, Paragraph 7, Item 2; Article 34-2, Paragraph 4, Item 2	
		Manufacturing authorization holders for Class II medical devices		33,200	33,200
				Article 33, Paragraph 8; Article 34-2, Paragraph 5	
	Others (including re-manufactured single-use medical devices)			47,500	47,500
				Article 33, Paragraph 7, Item 3; Article 34-2, Paragraph 4, Item 3	
		Manufacturing authorization holders for Class II medical devices		33,200	33,200
				Article 33, Paragraph 8; Article 34-2, Paragraph 5	
	Travel expenses for on-site inspection (per day)	In Japan		212,400	212,400
				Article 33, Paragraph 9, Item 1 and Paragraph 13; Article 34-2, Paragraph 6, Item 1	
		Overseas		179,500 + overseas travel expenses	179,500 + overseas travel expenses
				Article 33, Paragraph 9, Item 2 (a) (b); Article 34-2, Paragraph 6, Item 2 (a) (b)	
	Reissue/renewal of compliance certification			11,000	11,000
				Article 33, Paragraph 17	

Note) The applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices are shown in the lower rows in the field of user fees. (unit: yen)

Category				User fees		
				Review	Conformity	Total
GLP inspection of medical devices						
	GLP	In Japan			3,203,600 Article 33, Paragraph 4, Item 1 (a)	3,203,600
		Overseas			3,545,600 + overseas travel expenses Article 33, Paragraph 4, Item 1 (b)	3,545,600 + overseas travel expenses
GCP inspection of medical devices						
	GCP	In Japan			986,600 Article 33, Paragraph 4, Item 2 (a)	986,600
		Overseas			1,426,500 + overseas travel expenses Article 33, Paragraph 4, Item 2 (b)	1,426,500 + overseas travel expenses
Medical devices (emergency approval)						
	GPSP	In Japan			948,500 Article 33, Paragraph 4, Item 3 (a)	948,500
		Overseas			1,474,000 (+ overseas travel expenses *2) Article 33, Paragraph 4, Item 3 (b)	1,474,000 (+ overseas travel expenses *2)
Use-results evaluation of medical devices and in vitro diagnostics						
	Target medical devices			759,100 Article 33, Paragraph 14, Item 1 (a)	970,100 (+ overseas travel expenses *2) Article 33, Paragraph 15, Item 1	1,729,200 (+ overseas travel expenses *2)
	Target medical devices with multiple brand names			53,700 Article 33, Paragraph 14, Item 1 (b)		53,700
	Target in vitro diagnostics			759,100 Article 33, Paragraph 14, Item 2	970,100 (+ overseas travel expenses *2) Article 33, Paragraph 15, Item 1	1,729,200 (+ overseas travel expenses *2)
	Use-results evaluation of medical devices GLP	In Japan			3,203,600 Article 33, Paragraph 15, Item 2 (a) (1)	3,203,600
		Overseas			3,545,600 (+ overseas travel expenses *2) Article 33, Paragraph 15, Item 2 (a) (2)	3,545,600 (+ overseas travel expenses *2)
	GPSP	Medical devices	In Japan		948,500 Article 33, Paragraph 15, Item 2 (b) (1)	948,500
			Overseas		1,474,000 (+ overseas travel expenses *2) Article 33, Paragraph 15, Item 2 (b) (2)	1,474,000 (+ overseas travel expenses *2)
		In vitro diagnostics	In Japan		948,500 Article 33, Paragraph 15, Item 2 (b) (1)	948,500
			Overseas		1,474,000 (+ overseas travel expenses *2) Article 33, Paragraph 15, Item 2 (b) (2)	1,474,000 (+ overseas travel expenses *2)
Inspection of certification bodies for medical devices/in vitro diagnostics						
	Medical devices	New registration of certification bodies	In Japan		1,520,300 Article 34, Paragraph 1, Item 1	1,520,300
			Overseas		1,578,900 + overseas travel expenses Article 34, Paragraph 1, Item 2	1,578,900 + overseas travel expenses
		Renewal of registration of certification bodies	In Japan		609,300 Article 34, Paragraph 2, Item 1	609,300
			Overseas		670,700 + overseas travel expenses Article 34, Paragraph 2, Item 2	670,700 + overseas travel expenses
	In vitro diagnostics	New registration of certification bodies	In Japan		1,520,300 Article 34, Paragraph 1, Item 1	1,520,300
			Overseas		1,578,900 + overseas travel expenses Article 34, Paragraph 1, Item 2	1,578,900 + overseas travel expenses
		Renewal of registration of certification bodies	In Japan		609,300 Article 34, Paragraph 2, Item 1	609,300
			Overseas		670,700 + overseas travel expenses Article 34, Paragraph 2, Item 2	670,700 + overseas travel expenses

(*2) Amount including overseas travel expenses in cases where the inspection is conducted in a foreign country (Article 33, Paragraph 16)