Revised on May 20, 2022

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)

			y i roddots, and oos	sinetics are shown in the low	er rows in the field of user fees. User fees	(unit: yen)
	Cate	gory		Review	Conformity	Total
<mark>/iew for approva</mark>	l of medical device	<mark>es/in vitro diagno</mark> :	stics (new approval)			
	Now modical	davisas (Class	IVA	16,431,300	1,289,900 (+ overseas travel expenses *1)	17,721,200 (+ overseas trav expenses *
	new medical	devices (Class	10)	Article 33, Paragraph 1, Item 1 (a) (1)	Article 33, Paragraph 2, Item 1 (a)	
				Same as above	89,400 (*2) (+ overseas travel	16,520,700 (+ overseas trav
		Without	clinical data	Same as above	expenses *1) Article 33, Paragraph 2, Item 1 (c)	expenses *
				11,727,000	1 290 000 /+ aversess travel	13,016,900 (+ overseas trav
	New medical devices (Class II/III) Without clinical data				expenses *1)	expenses *
				Article 33, Paragraph 1, Item 1 (a) (3)	Article 33, Paragraph 2, Item 1 (a)	
				Same as above	89,400 (*2) (+ overseas travel expenses *1)	11,816,400 (+ overseas trav expenses *
		vvitnout	. Clinical data		Article 33, Paragraph 2, Item 1 (c)	expenses
		•		9,381,400	1,032,000 (+ overseas travel	10,413,400 (+ overseas tra
Improved	I medical device	s/with clinical c	lata (Class IV)	Article 33, Paragraph 1, Item	expenses "1)	expenses
				1 (a) (2)	Article 33, Paragraph 2, Item 1 (b)	0.470.000 /
		Without	clinical data	Same as above	89,400 (*2) (+ overseas travel expenses *1)	9,470,800 (+ overseas tra expenses
					Article 33, Paragraph 2, Item 1 (c)	
				5,618,800	1,032,000 (+ overseas travel expenses *1)	6,650,800 (+ overseas tra expenses
Improved medical devices/with clinical data (Class II/III)			ata (Class II/III)	Article 33, Paragraph 1, Item	Article 33, Paragraph 2, Item 1 (b)	охроново
				1 (a) (4)	89,400 (*2) (+ overseas travel	5,708,200 (+ overseas tra
		Without	clinical data	Same as above	expenses *1)	expenses
					Article 33, Paragraph 2, Item 1 (c)	2.000.600 (1.0)/070000 tro
Improved med	dical devices/wit	hout clinical da	ta/without approval	2,991,200	89,400 (*2) (+ overseas travel expenses *1)	3,080,600 (+ overseas tra expenses
	standard	ds (Class IV)		Article 33, Paragraph 1, Item	Article 33, Paragraph 2, Item 1 (c)	·
				1 (a) (7)	89,400 (*2) (+ overseas travel	2,334,300 (+ overseas tra
Generic medi		nout clinical data ds (Class IV)	a/without approval	2,244,900	expenses *1)	expenses
	Standard	us (Class IV)		Article 33, Paragraph 1, Item 1 (a) (8)	Article 33, Paragraph 2, Item 1 (c)	
Improved gor	aria madical da	visas/with out a	liniaal data/withaut	1,790,500	89,400 (*2) (+ overseas travel	1,879,900 (+ overseas tra
improved ger		dards (Class II/	linical data/without ′III)	Article 33, Paragraph 1, Item	expenses *1)	expenses
		· 	•	1 (a) (9)	Article 33, Paragraph 2, Item 1 (c)	004 400 / 1 - 1 - 1 - 1 - 1
Canaria ma	diaal dayiaaa/wii	th annroyal atox	adarda (Class IV)	545,000	89,400 (*2) (+ overseas travel expenses *1)	634,400 (+ overseas tra expenses
Generic med	uicai devices/wii	ırı approvai star	ndards (Class IV)	Article 33, Paragraph 1, Item 1 (a) (5)	Article 33, Paragraph 2, Item 1 (c)	
					89,400 (*2) (+ overseas travel	526,400 (+ overseas tra
Generic med	ical devices/with	h approval stan	dards (Class II/III)	437,000	expenses *1)	expenses
			, ,	Article 33, Paragraph 1, Item 1 (a) (6)	Article 33, Paragraph 2, Item 1 (c)	
				9,381,400	1,032,000 (+ overseas travel expenses *1)	10,413,400 (+ overseas tra expenses
		(C	lass IV)	Article 33, Paragraph 1, Item	Article 33, Paragraph 2, Item 1 (b)	expenses
	ured single-use I devices			1 (a) (2)		6 650 900 (1 average tre
medica	i devices	(Cl	ass II/III)	5,618,800	1,032,000 (+ overseas travel expenses *1)	6,650,800 (+ overseas tra expenses
		(Cir	ass II/III)	Article 33, Paragraph 1, Item 1 (a) (4)	Article 33, Paragraph 2, Item 1 (b)	
				2,534,000		2,534,0
		Excluding com	panion diagnostics	Article 33, Paragraph 1, Item		
	New products	roducts		1 (b) (2) 4,295,000		4,295,0
		Compani	on diagnostics	Article 33, Paragraph 1, Item		
				1 (b) (3) 2,534,000		2,534,0
		\A/:411::1	Excluding companion diagnostics	Article 33, Paragraph 1, Item		
	Outside the	With clinical data		1 (b) (2) 4,295,000		4,295,0
	scope of approval		Companion diagnostics	Article 33, Paragraph 1, Item		,,
	standards			1 (b) (3) 2,362,200		2,362,2
		Without	clinical data	Article 33, Paragraph 1, Item		_,00_,-
In vitro diagnostics			1	1 (b) (4) 2,534,000		2,534,0
			Excluding companion diagnostics	Article 33, Paragraph 1, Item		2,004,0
	Nonconformity	With clinical data		1 (b) (2) 4,295,000		4,295,0
	Nonconformity with approval		Companion diagnostics	Article 33, Paragraph 1, Item		4,200,0
	standards		a.a.g.reea.ee	1 (b) (3) 1,318,600		1,318,6
		Without	clinical data	Article 33, Paragraph 1, Item		1,010,0
	Conformation ''			1 (b) (6) 454,800		454,8
	Conformity with approval		clinical data	Article 33, Paragraph 1, Item		404,8
	standards	<u> </u>		1 (b) (5)		60.0
		Addition of se	ries	63,300 Article 33, Paragraph 1, Item		63,3
				1 (b) (1)		07.0
	Addition o	of brand name		37,300 Article 33, Paragraph 1, Item		37,3
4) 4				1 (c)		1.0)
II Amounting	unding overcor	troval avaace	aa in aaaaa whar- H		in a foreign country (Article 22 Darge	

^(*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.

	Cateç	gory		Review	User fees Conformity	Total	
	l of medical dev artial changes to		agnostics (approval				
ιοι μα	New medical o			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 tra expenses	
	Without clinical data			Same as above	48,400 (*2) (+ overseas travel expenses *1)	8,272,700 (+ overseas tra expenses	
				5,869,700	Article 33, Paragraph 2, Item 2 (c) 1,289,900 (+ overseas travel	7,159,600 (+ overseas tra	
	New medical d	evices (Class I	I/III)	Article 33, Paragraph 1, Item 2 (a) (3)	expenses *1) Article 33, Paragraph 2, Item 2 (a)	expenses	
		Without	clinical data	Same as above	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	5,918,100 (+ overseas tra expenses	
Improved medical devices/with clinical data (Class IV)				4,695,800 Article 33, Paragraph 1, Item 2 (a) (2)	1 022 000 / 1 - 1 - 1 - 1 - 1	5,727,800 (+ overseas tr expenses	
				Same as above	48,400 (*2) (+ overseas travel expenses *1) Article 33, Paragraph 2, Item 2 (c)	4,744,200 (+ overseas tr expenses	
Improved r	medical devices	/with clinical da	ata (Class II/III)	2,827,300 Article 33, Paragraph 1, Item 2	1,032,000 (+ overseas travel expenses *1)	3,859,300 (+ overseas tr expenses	
·				(a) (4) Same as above	Article 33, Paragraph 2, Item 2 (b) 48,400 (*2) (+ overseas travel	2,875,700 (+ overseas tr	
			clinical data	1,500,100	expenses *1) Article 33, Paragraph 2, Item 2 (c) 48,400 (*2) (+ overseas travel	expense: 1,548,500 (+ overseas tr	
Improved medi		nout clinical da ls (Class IV)	ta/without approval	Article 33, Paragraph 1, Item 2 (a) (7)	expenses *1) Article 33, Paragraph 2, Item 2 (c)	expenses	
Generic medic			a/without approval	1,122,900	expenses 1)	1,171,300 (+ overseas tr expenses	
	Stariuaru	ls (Class IV)		Article 33, Paragraph 1, Item 2 (a) (8)	Article 33, Paragraph 2, Item 2 (c) 48,400 (*2) (+ overseas travel	949,500 (+ overseas tra	
Improved gene		vices/without cl dards (Class II/	inical data/without III)	901,100 Article 33, Paragraph 1, Item 2	expenses *1) Article 33, Paragraph 2, Item 2 (c)	expenses	
			<u> </u>	(a) (9) 276,300	48,400 (*2) (+ overseas travel	324,700 (+ overseas tr	
Generic med	lical devices/wit	h approval star	ndards (Class IV)	Article 33, Paragraph 1, Item 2 (a) (5)	expenses *1) Article 33, Paragraph 2, Item 2 (c)	expenses	
Generic medic	cal devices/with	annroval stan	dards (Class II/III)	220,400	EXPENSES IN	268,800 (+ overseas tr expenses	
- Concine medic	car devices, with	approvar starr	dards (Oldss II/III)	Article 33, Paragraph 1, Item 2 (a) (6)	10, 100, (*2) (1, 2) (200, 200, 400, 401	220 600 / 1 2 2 2 2 2 2 2	
	Others (me	edical devices)		182,200 Article 33, Paragraph 1, Item 2	expenses 1)	230,600 (+ overseas tr expenses	
		Withou	t inspection	(a) (10) Same as above	Article 33, Paragraph 2, Item 2 (c)	182,	
		VVIIIOU	it inspection	4,695,800	1,032,000 (+ overseas travel	5,727,800 (+ overseas tr	
		(Class IV)		Article 33, Paragraph 1, Item 2	expenses *1) Article 33, Paragraph 2, Item 2 (b)	expenses	
	With re- manufacturing design and manufacturing data		Without study data of		(a) (2) Same as above	48,400 (*2) (+ overseas travel expenses *1)	4,744,200 (+ overseas tr expenses
			design/manufacturing	2,827,300	Article 33, Paragraph 2, Item 2 (c)	3,859,300 (+ overseas tr	
		(Cla	ass II/III)	Article 33, Paragraph 1, Item 2 (a) (4)	expenses *1) Article 33, Paragraph 2, Item 2 (b)	expenses	
Re- manufactured single-use			Without study data on design/manufacturing	Same as above	48,400 (*2) (+ overseas travel expenses *1)	2,875,700 (+ overseas tr expenses	
medical devices	Without re- manufacturing design or manufacturing data			1,122,900	Article 33, Paragraph 2, Item 2 (c) 48,400 (*2) (+ overseas travel expenses *1)	1,171,300 (+ overseas tr expenses	
		manufacturing	(Class IV)		Article 33, Paragraph 1, Item 2 (a) (8)	Article 33, Paragraph 2, Item 2 (c)	·
		(Cla	ass II/III)	901,100 Article 33, Paragraph 1, Item 2	expenses 1)	949,500 (+ overseas tr expenses	
				(a) (9) 182,200	Article 33, Paragraph 2, Item 2 (c) 48,400 (*2) (+ overseas travel	230,600 (+ overseas tr	
		Others		Article 33, Paragraph 1, Item 2 (a) (10)	expenses *1) Article 33, Paragraph 2, Item 2 (c)	expenses	
		With clinical	Excluding companion diagnostics	1,048,200 Article 33, Paragraph 1, Item 2 (b) (2)		1,048,	
	Outside the	data	Companion diagnostics	1,996,600 Article 33, Paragraph 1, Item 2		1,996,	
	scope of approval standards		Excluding companion diagnostics	(b) (3) 295,600 Article 33, Paragraph 1, Item 2		295,0	
		Without clinical data	Companion diagnostics	(b) (4) 1,007,200 Article 33, Paragraph 1, Item 2		1,007,2	
			Excluding companion diagnostics	(b) (5) 1,048,200 Article 33, Paragraph 1, Item 2		1,048,	
In vitro diagnostics	Nonconformity with approval standards	With clinical data	Companion	(b) (2) 1,996,600 Article 33, Paragraph 1, Item 2		1,996,	
ı		with approva		diagnostics Excluding companion	(b) (3) 295,600		295,
		Without clinical data	diagnostics	Article 33, Paragraph 1, Item 2 (b) (4) 1,007,200		1,007,	
			Companion	Article 22 Deserved 4 11 2			
	standards Conformity with	clinical data	diagnostics	Article 33, Paragraph 1, Item 2 (b) (5) 295,600		295,	
	standards	clinical data Without	diagnostics	Article 33, Paragraph 1, Item 2 (b) (5)			
	standards Conformity with approval	clinical data	diagnostics	Article 33, Paragraph 1, Item 2 (b) (5) 295,600 Article 33, Paragraph 1, Item 2 (b) (6)		295,0 33,4	

^(*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).

	Including Pharmaceuticals and Medical Devices are shown in t	, ,				
	O-t		User fees	User fees		
	Category	Review	Conformity	Total		
Rev	iew for approval of medical devices (emergency approval)		·			
	New medical devices (Class IV)	16,431,300	970,100 (+ overseas travel expenses *1)	17,401,400 (+ overseas travel expenses *1)		
	New medical devices (Glass IV)	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)		
Ą	New medical devices (Glass II/III)	Article 33, Paragraph 1, Item 1 (a) (3)	Article 33, Paragraph 2, Item 3			
At the time	Improved medical devices/with clinical data (Class IV)	9,381,400	970,100 (+ overseas travel expenses *1)	10,351,500 (+ overseas travel expenses *1)		
	improved medical devices/with clinical data (Glass IV)	Article 33, Paragraph 1, Item 1 (a) (2)	Article 33, Paragraph 2, Item 3			
f appl	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)		
of application	Improved medical devices, with diffical data (Glass II/III)	Article 33, Paragraph 1, Item 1 (a) (4)	Article 33, Paragraph 2, Item 3			
n	Improved medical devices/without clinical data/without	2,991,200	970,100 (+ overseas travel expenses *1)	3,961,300 (+ overseas travel expenses *1)		
	approval standards (Class IV)	Article 33, Paragraph 1, Item 1 (a) (7)	Article 33, Paragraph 2, Item 3			
	Improved medical devices/without clinical data/without	1,790,500	970,100 (+ overseas travel expenses *1)	2,760,600 (+ overseas travel expenses *1)		
	approval standards (Class II/III)	Article 33, Paragraph 1, Item 1 (a) (9)	Article 33, Paragraph 2, Item 3			
	New medical devices (Class IV)	8,224,300	970,100 (+ overseas travel expenses *1)	9,194,400 (+ overseas travel expenses *1)		
	Trest medical devices (elase iv)	Article 33, Paragraph 1, Item 2 (a) (1)	Article 33, Paragraph 2, Item 3			
Ąŧ	New medical devices (Class II/III)	5,869,700	970,100 (+ overseas travel expenses *1)			
At the time	New medical devices (Glass II/III)	Article 33, Paragraph 1, Item 2 (a) (3)	Article 33, Paragraph 2, Item 3			
me of	Improved medical devices/with clinical data (Class IV)	4,695,800	970,100 (+ overseas travel expenses *1)	5,665,900 (+ overseas travel expenses *1)		
appl	improved medical devices/with clinical data (Glass IV)	Article 33, Paragraph 1, Item 2 (a) (2)	Article 33, Paragraph 2, Item 3			
icatio	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)		
n for o	Improved medical devices, with diffical data (class fifth)	Article 33, Paragraph 1, Item 2 (a) (4)	Article 33, Paragraph 2, Item 3			
application for change	Improved medical devices/without clinical data/without	1,500,100	970,100 (+ overseas travel expenses *1)	2,470,200 (+ overseas travel expenses *1)		
e	approval standards (Class IV)	Article 33, Paragraph 1, Item 2 (a) (7)	Article 33, Paragraph 2, Item 3			
	Improved generic medical devices/without clinical	901,100	970,100 (+ overseas travel expenses *1)	1,871,200 (+ overseas travel expenses *1)		
	data/without approval standards (Class II/III)	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)

	Cateç			the lower rows in the field of	User fees	(unit: yen)
eview of plan to change approved information on medical			ian an madiaal	Review	Conformity	Total
view of plan	devices/in vitro		ion on medical			
	Name alianta	I-vi (OI	IV (V	8,224,300		8,224,30
	New medical d	ievices (Class	10)	Article 34-2, Paragraph 1, Item 1 (a)		
				5,869,700		5,869,70
1	New medical de	evices (Class I	I/III)	Article 34-2, Paragraph 1, Item 1 (c)		
				4,695,800		4,695,80
Improved r	proved medical devices/with clinical data (Class IV)			Article 34-2, Paragraph		
				1, Item 1 (b) 2,827,300		2,827,30
Improved m	nedical devices	/with clinical d	ata (Class II/III)	Article 34-2, Paragraph		2,021,00
				1, Item 1 (d)		4 500 46
Improved r	nedical devices			1,500,100 Article 34-2, Paragraph		1,500,10
	approval stan	dards (Class I	V)	1, Item 1 (g)		
Generic m	nedical devices	/without clinica	l data/without	1,122,900		1,122,90
	approval stan	dards (Class I	V)	Article 34-2, Paragraph 1, Item 1 (h)		
Improve	ed generic medi	cal devices/with	nout clinical	901,100		901,10
	without approva			Article 34-2, Paragraph 1, Item 1 (i)		
		1.70		276,300		276,30
Generic	medical device (Cla	es/with approva ass IV)	al standards	Article 34-2, Paragraph		
	`	•		1, Item 1 (e) 220,400		220,40
Generic	medical device	es/with approva ss II/III)	al standards	Article 34-2, Paragraph		220,40
	(Oldi			1, Item 1 (f)		400.00
	Others (me	dical devices)		182,200 Article 34-2, Paragraph		182,20
	,	,		1, Item 2		
		With clinical	Excluding companion diagnostics Companion diagnostics	1,048,200		1,048,20
				Article 34-2, Paragraph 1, Item 3 (c)		
		data		1,996,600		1,996,60
	Outside the scope of			Article 34-2, Paragraph 1, Item 3 (b)		
	approval	pproval andards	Excluding	295,600		295,60
	standards		companion	Article 34-2, Paragraph		
		Without clinical data	diagnostics	1, Item 3 (e) 1,007,200		1,007,20
			Companion diagnostics	Article 34-2, Paragraph		.,,,,,,
				1, Item 3 (d) 1,048,200		1,048,20
			Excluding companion	Article 34-2, Paragraph		1,046,20
In vitro		With clinical	diagnostics	1, Item 3 (c)		
diagnostics		data	Companion	1,996,600 Article 34-2, Paragraph		1,996,60
	Nonconformity with approval		diagnostics	1, Item 3 (b)		
	standards		Excluding	295,600		295,60
		Without	companion diagnostics	Article 34-2, Paragraph 1, Item 3 (e)		
		clinical data	Companion	1,007,200		1,007,20
			diagnostics	Article 34-2, Paragraph 1, Item 3 (d)		
	Conformity			295,600		295,60
	with approval standards	Without	clinical data	Article 34-2, Paragraph		
	Standards			1, Item 3 (f) 33,400		33,40
	,	Addition of ser	ies	Article 34-2, Paragraph		33,40
				1, Item 3 (a)		
	Others (in vi	tro diagnostics	3)	150,600 Article 34-2, Paragraph		150,60
	\	J	,	1, Item 4		

	Cate	egory	-	Review	User fees Conformity	Total		
QMS inspection of medical devices/in vitro diagnostics			ro diagnostics	Review	Conformity	rotar		
QIVIS	inspection of medical	devices/in vit	ro diagnostics		50,400	50,4		
Issuance fee for certification of conformity with approval standards			nity with approval		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	30,41		
					386,600	386,6		
		New			Article 33, Paragraph 5, Item 1 (a) (2)			
		medical devices	Manufacturing authorization holders		386,600	386,6		
			for Class II medical devices		Article 33, Paragraph 6, Item 1 (a) (2)			
			Isaa N/		374,500	374,5		
			lass IV		Article 33, Paragraph 5, Item 1 (a) (3)			
					398,500	398,5		
	Now application	Biological			Article 33, Paragraph 5, Item 1 (a) (1)			
	New application	drugs	Manufacturing authorization holders		398,500	398,5		
			for Class II medical devices		Article 33, Paragraph 6, Item 1 (a) (1)			
					374,500	374,5		
		Other			Article 33, Paragraph 5, Item 1 (a) (4)			
		medical devices	Manufacturing authorization holders		262,100	262,1		
		4071000	for Class II medical devices		Article 33, Paragraph 6, Item 1 (a) (3)			
					272,900	272,9		
		In vitro	diagnostics		Article 33, Paragraph 5, Item 1 (a) (5)			
-					134,000	134,0		
	Partial change		lass IV		Article 33, Paragraph 5, Item 2 (a) (2)			
							145,600	145,6
		Biological			Article 33, Paragraph 5, Item 2 (a) (1)			
		drugs	Manufacturing authorization holders		145,600	145,6		
		Partial change	for Class II medical devices		Article 33, Paragraph 6, Item 2 (a) (1)			
			GOVIDOS		127,800	127,8		
		Other			Article 33, Paragraph 5, Item 2 (a) (3)			
Fee			medical Manufactur devices authorization h	Manufacturing		89,400	89,4	
paic			devices	for Class II medical		Article 33, Paragraph 6, Item 2 (a) (2)		
paid by MAH		In vitro diagnostics			93,200	93,2		
\leq					Article 33, Paragraph 5, Item 2 (a) (4)			
Ξ -					134,000	134,0		
		Class IV			Article 34-2, Paragraph 2, Item 1 (b)			
	Review of plan to change	Review of plan to change				145,600	145,6	
			Biological			Article 34-2, Paragraph 2, Item 1 (a)		
				drugs	Manufacturing authorization holders		145,600	145,6
					for Class II medical devices		Article 34-2, Paragraph 3, Item 1 (a)	
						127,800	127,8	
			Other			Article 34-2, Paragraph 2, Item 1 (c)		
		medical devices	Manufacturing authorization holders		89,400	89,4		
		uc vices	for Class II medical		Article 34-2, Paragraph 3, Item 1 (b)			
		devices			93,200	93,2		
		In vitro	diagnostics		Article 34-2, Paragraph 2, Item 1 (d)			
-					167,600	167,6		
		Class IV			Article 33, Paragraph 5, Item 3 (a) (2)			
	Renewal				176,900	176,9		
		Biological			Article 33, Paragraph 5, Item 3 (a) (1)			
			drugs	Manufacturing authorization holders		176,900	176,9	
			for Class II medical devices		Article 33, Paragraph 6, Item 3 (a) (1)			
					149,200	149,2		
		Other			Article 33, Paragraph 5, Item 3 (a) (3)			
		medical devices	Manufacturing		104,400	104,4		
		uevices	authorization holders for Class II medical devices		Article 33, Paragraph 6, Item 3 (a) (2)			
			<u> </u>		129,700	129,7		
I I		In vitro	diagnostics		Article 33, Paragraph 5, Item 3 (a) (4)	120,1		

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

	Catao	lory.			User fees	
Category				Review	Conformity	Total
<mark>QMS in</mark>	nspection of medical o	<mark>levices/in vitr</mark>	o diagnostics			
	Design		Manufacturing authorization holders		68,800 Article 33, Paragraph 5, Item 3 (b) (1) and Paragraph 11, Item 2 (a) 48,100	68,80 48,10
			for Class II medical devices		Article 33, Paragraph 6, Item 3 (b) (1)	
			401.000		80,100	80,10
	Sterilisation				Article 33, Paragraph 5, Item 3 (b) (3) and Paragraph 11, Item 2 (c)	
	Stermsation	I	Manufacturing authorization holders for Class II medical devices		56,000 Article 33, Paragraph 6, Item 3 (b) (3)	56,00
					97,400	97,40
Renewal	Accombly closni	ag ata			Article 33, Paragraph 5, Item 3 (b) (2) and Paragraph 11, Item 2 (b)	
ewal	Assembly, cleanir	ig, etc.	Manufacturing authorization holders for Class II medical		68,100 Article 33, Paragraph 6, Item 3 (b) (2)	68,10
			devices		79,600	79,60
					Article 33, Paragraph 5, Item 3 (b) (4) and Paragraph 11, Item 2 (d)	79,00
	Others		Manufacturing		55,700	55,70
			authorization holders for Class II medical devices		Article 33, Paragraph 6, Item 3 (b) (4)	
					76,100	76,10
	authorization for Class I				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 Article 33, Paragraph 6, Item 3 (b) (5)	53,20
	Micro Manufacturing authorization holders for Class II medical devices		_		47,500 Article 33, Paragraph 7, Item 1; Article 34-2, Paragraph 4, Item 1	47,50
					33,200	33,20
			for Class II medical		Article 33, Paragraph 8; Article 34-2, Paragraph 5	
Opt	Nanomaterial Manufacturing authorization holders for Class II medical devices			47,500 Article 33, Paragraph 7, Item 2; Article 34-2, Paragraph 4, Item 2	47,50	
Options					33,200	33,20
			for Class II medical		Article 33, Paragraph 8; Article 34-2, Paragraph 5	
					47,500	47,50
/:	Others				Article 33, Paragraph 7, Item 3; Article 34-2, Paragraph 4, Item 3	
('	(including re-manufactured single- use medical devices)		Manufacturing authorization holders		33,200	33,20
			for Class II medical devices		Article 33, Paragraph 8; Article 34-2, Paragraph 5	
Trave	el expenses for on-	ln	Japan		212,400 Article 33, Paragraph 9, Item 1 and Paragraph 13; Article 34-2, Paragraph 6, Item 1	212,40
	site inspection (per day)	Ov	rerseas		179,500 + overseas travel expenses	179,500 + overseas trave expense
			2.0000		Article 33, Paragraph 9, Item 2 (a) (b); Article 34-2, Paragraph 6, Item 2 (a) (b)	
	Reissue/renewal of c	compliance c	ertification		11,000	11,00
					Article 33, Paragraph 17	

	Including Pha	irmaceuticals a	nd Medical Dev	rices are shown in t	the lower rows in the field o		(unit: yen)								
		Cate	gory		Daviano	User fees	-	T-4-1							
	CLD			200	Review	Conformity		Total							
	GLP	inspection of	medical devic	ces		3,203,600	3,203,600								
			In .	Japan		Article 33, Paragraph 4, Item 1 (a)	3,203,000								
	GL	.Р				3,545,600 + overseas travel	2 545 600	+ overseas trave							
			Ove	erseas		expenses	3,545,600	expenses							
						Article 33, Paragraph 4, Item 1 (b)									
	GCF	inspection of	<mark>f medical devi</mark> d	ces		000,000	000 000								
			ln .	Japan		986,600 Article 33, Paragraph 4, Item 2 (a)	986,600								
	GCP	:P		-		L average travel		+ overseas trave							
		,	Ove	erseas		1,426,500 + overseas traver expenses	1,426,500	expenses							
						Article 33, Paragraph 4, Item 2 (b)	-	1							
	Medica	al devices (en	nergency appr	oval)											
			In	Japan		948,500	948,500								
	0.5	0.5	111 ,	оаран ———————————————————————————————————		Article 33, Paragraph 4, Item 3 (a)									
	GP	SP	0			1,474,000 (+ overseas travel expenses *2)	1,474,000	(+ overseas trave							
			Ove	erseas		Article 33, Paragraph 4, Item 3 (b)		expenses *2)							
	lee-results ev	valuation of m	nedical devices	s and in vitro		7 thoic 60, 1 drugraph 4, hem 6 (b)									
C	73C-1C3ult3 C	diagno		s and in vido											
					750 100	970,100 (+ overseas travel	1,729,200	(+ overseas travel							
		Tarnet me	edical devices		759,100	970,100 expenses *2)	1,129,200	expenses *2)							
		raigetine	sulcai devices		Article 33, Paragraph	Article 33, Paragraph 15, Item 1									
\vdash					14, Item 1 (a) 53,700	, J , -7	E0 700								
	Target me	dical devices	s with multiple brand names		Article 33, Paragraph		53,700								
	raigetille	dicai devices			14, Item 1 (b)										
 						970,100 (+ overseas travel	4 700 000	(+ overseas travel							
		Target in vi	tro diagnostics	2	759,100	970,100 expenses *2)	1,729,200	expenses *2)							
		raiget iii vi	uo diagnostic.	•	Article 33, Paragraph	Article 33, Paragraph 15, Item 1									
<u> </u>			Γ		14, Item 2		2 202 600								
			In .	Japan		3,203,600 Article 33, Paragraph 15, Item 2 (a) (1)	3,203,600								
	Use-results e		Overseas					(+ overseas trave							
	medical de	vices GLP				3,545,600 (+ overseas travel expenses *2)	3,545,600	expenses *2)							
L				77010040		Article 33, Paragraph 15, Item 2 (a) (2)									
				In Japan		948,500	948,500								
			Medical	пт барап		Article 33, Paragraph 15, Item 2 (b) (1)									
			devices			1,474,000 (+ overseas travel expenses *2)	1,474,000	(+ overseas travel							
						Article 33, Paragraph 15, Item 2 (b) (2)		expenses *2)							
	GP	SP	L. Mar			948,500	948,500								
				In vitro		In Japan		Article 33. Paragraph 15. Item 2 (b) (1)	•						
		diagnostics								1 474 000 (+ overseas travel	1,474,000	(+ overseas travel			
			diagnoonoo	Overseas			1,474,000	expenses *2)							
		C.C C L L.		Alexander of Properties		Article 33, Paragraph 15, Item 2 (b) (2)									
msp	ection of cer	tification bodie diagno		devices/in vitro											
		diagric				1,520,300	1,520,300								
		Now road	stration of	tration of	tration of	stration of	tration of	tration of	tration of	tration of	In Japan		Article 34, Paragraph 1, Item 1	,==,,	
			stration of on bodies			1 578 900 + overseas travel	1,578,900	+ overseas trave							
		ooi anoati	C.I DOUICS	Overseas		Схрспаса	1,070,900	expenses							
	Medical					Article 34, Paragraph 1, Item 2	600 000								
	devices			In Japan		609,300 Article 34, Paragraph 2, Item 1	609,300								
			egistration of					+ overseas trave							
		certification	on bodies	Overseas		670,700 + overseas travel expenses	670,700	expenses							
L						Article 34, Paragraph 2, Item 2									
				In Japan		1,520,300	1,520,300								
		New regis	stration of	σαραιί		Article 34, Paragraph 1, Item 1									
			on bodies	Oversess		1,578,900 + overseas travel expenses	1,578,900	+ overseas travel expenses							
	In vitro			Overseas		Article 34, Paragraph 1, Item 2		CAPELISES							
	diagnostics					609,300	609,300								
		Donowal of a	rogistration of	In Japan		Article 34, Paragraph 2, Item 1	-								
			egistration of on bodies			670,700 + overseas travel	670,700	+ overseas trave							
		ooi anoati	C.I DOUICS	Overseas		СХРСПЭСЭ	370,700	expenses							
		cluding overseas travel exp				Article 34, Paragraph 2, Item 2									

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