Fee payable for licence, permission and registration certificate

Sr. No.	Rule	Subject	In rupees (INR) except where specified in dollars ($)
(1)	(2)	(3)	(4)
1.	13(5)	Registration of Notified Body.	25000
2.	13(7)	Registration retention fee of Notified Body.	25000
3.	20(2)	Manufacturing licence or loan licence to manufacture Class A or Class B medical device for,-	----
4.		(a) one site; and	5000
5.		(b) each distinct medical device.	500
6.	21(2)	Manufacturing licence or loan licence to manufacture Class C or Class D medical device for,-	----
7.		(a) one site; and	50000
8.		(b) each distinct medical device.	1000
9.	29(1)	Manufacturing licence or loan licence retention fee for,-	----
10.		(a) one site manufacturing Class A or Class B medical device; or	5000
11.		(b) one site of manufacturing Class C or Class D medical device; or	50000
12.		(c) each distinct medical device of Class A or Class B; or	500
13.		(d) each distinct medical device of Class C or Class D.	1000
14.	31(1)	Test licence to manufacture for clinical investigations, test, evaluation, examination, demonstration or training for each distinct medical device.	500
15.	34(2)	Import licence for Class A medical device other than *in vitro* diagnostic medical device for,-	
16.		(a) one site; and	$1000
17.		(b) each distinct medical device.	$50
18.	34(2)	Import licence for Class B medical device other than *in vitro* diagnostic medical device for,-	
19.		(a) one site; and	$2000
20.		(b) each distinct medical device.	$1000
21.	34(2)	Import licence for Class A or Class B *in vitro*	

		diagnostic medical device for,-	
22.		(a) one site; and	$1000
23.		(b) each distinct *in vitro* diagnostic medical device.	$10
24.	34(2)	Import licence for Class C or Class D medical device other than *in vitro* diagnostic medical device for,-	----
25.		(a) one site; and	$3000
26.		(b) each distinct medical device.	$1500
27.	34(2)	Import licence for Class C or Class D *in vitro* diagnostic medical device for,-	
28.		(a) one site; and	$3000
29.		(b) each distinct *in vitro* diagnostic medical device.	$500
30.	35(2)	Inspection of the overseas manufacturing site.	$6000
31.	37	Import licence retention fee for,-	----
32.		(a) one overseas site manufacturing Class A medical device other than *in vitro* diagnostic medical device; or	$1000
33.		(b) one overseas site manufacturing Class B medical device other than *in vitro* diagnostic medical device; or	$2000
34.		(c) one overseas site manufacturing Class C or Class D medical device other than *in vitro* diagnostic medical device; or	$3000
35.		(d) each distinct medical device of Class A other than *in vitro* diagnostic medical device; or	$50
36.		(e) each distinct medical device of Class B other than *in vitro* diagnostic medical device; or	$1000
37.		(f) each distinct medical device of Class C or Class D other than *in vitro* diagnostic medical device.	$1500
38.		(g) one overseas site manufacturing Class A or Class B *in vitro* diagnostic medical device;	$1000
39.		(h) one overseas site manufacturing Class C or Class D medical device other than *in vitro* diagnostic medical device;	$3000
40.		(i) each distinct *in vitro* diagnostic medical device of Class A or Class B *in vitro* diagnostic medical device;	$10
41.		(j) each distinct *in vitro* diagnostic medical device of Class C or Class D *in vitro* diagnostic medical device;	$500
42.	40(2)	Fee for Import licence for test, evaluation or demonstration or training for each distinct medical device.	$100

43.	42(1)	Fee for Import of investigational medical device by Government hospital or statutory medical institution for treatment of patient of each distinct medical device.	500
44.	51(2)(a)	Permission to conduct pilot clinical investigation.	100000
45.	51(2)(b)	Permission to conduct pivotal clinical investigation.	100000
46.	59(2)	Permission to conduct clinical performance evaluation.	25000
47.	63(1)	Permission to import or manufacture a medical device which does not have its predicate device.	50000
48.	64(1)	Permission to import or manufacture new *in vitro* diagnostic medical device.	25000
49.	81(1)	Registration of medical device testing laboratory to carry out testing or evaluation of a medical device on behalf of manufacturer.	20000
50.	84	Registration retention fee for medical device testing laboratory	20000
51.	91	Certificate to export of each distinct medical device.	1000