MCA Malta Conformity Assessment

Medical Standard Fees

A) APPLICATION FEES

Product Risk Class	Fees	Type	Remarks
Class Is, Im, Ir and Sterile Systems or Procedure Packs	1000 Euro	FLAT	If more than one device is involved, the fee for the highest product risk class is applied.
Class IIa	1500 Euro		
Class IIb non-implantable	2000 Euro		
Class IIb implant	2500 Euro		
Class IIb active devices intended to administer and/or remove a medicinal product	3000 Euro		
Class III	3500 Euro		
Class III implantable	4000 Euro		

B) ANNUAL CERTIFICATE USAGE FEE

Product Risk Class	Fees	Type	Remarks
Class Is, Im, Ir and Sterile Systems or Procedure Packs	5000 Euro	FLAT	If more than one device is involved, the fee for highest product risk class is applied.
Class IIa	7000 Euro		
Class IIb non-implantable	9000 Euro		
Class IIb implantable	11000 Euro		
Class IIb active devices intended to administer and/or remove a medicinal product	13000 Euro		
Class III	15000 Euro		
Class III implantable	17000 Euro		

C) AUDIT MAN/DAY FEE

Location	Fees	Type	Remarks
EU Countries	2500 Euro	DAILY (MAN/DAY)	The number of man-days required for the audit is calculated mainly based on IAF MD 9 by applying several increasing and decreasing factors. One man-day is typically calculated as 8 hours.
Others	2500 Euro		

D) TECHNICAL DOCUMENTATION REVIEW MAN/DAY FEE

Location	Fees	Type	Remarks
EU Countries	2500 Euro	DAILY (MAN/DAY)	Time spent will be calculated based on the product risk class. The following factors will increase the duration per device, - PSUR, PMCF, SSCP, PMS Reviews - Routine reviews on Technical Documentation changes - Devices in sterile condition and the number of applied sterilization methods - Devices requiring biocompatibility review - Devices incorporating software - Devices that are absorbable or locally dispersed - Pre-market clinical investigation review - Medicinal Product Authority Consultation - Clinical Evaluation Consultation Procedure - Consultation procedure for devices that are systemically absorbed
Others	2500 Euro		

E) ADMINISTRATIVE AND OTHER FEES

Task		Fees	Type	Remarks
Initial review on changes	Class Is, Im, Ir and Sterile Systems or Procedure Packs	100 Euro	FLAT	If more than one device is involved in certification scope, the fee for highest product risk class is applied.
	Class IIa	150 Euro	FLAT	
	Class IIb non-implantable	200 Euro	FLAT	
	Class IIb implantable	250 Euro	FLAT	
	Class IIb active devices intended to administer and/or remove a medicinal product	250 Euro	FLAT	
	Class III	300 Euro	FLAT	
	Class III implantable	350 Euro	FLAT	
Administrative task for outgoing transfers		500 Euro	FLAT	Fees to be paid to the authorities are to be invoiced separately based on the rates available during the consultation process.
Preparation and follow-up activities for authority consultations		100 Euro	HOURLY	
Assessment on appeals		100 Euro	HOURLY	
Travel Time (excluding travel and accommodation expenses)		50 Euro	HOURLY	

F) FEES FOR REPEATING NON-CONFORMITY CORRECTIONS

Task	Fees	Type	Remarks
Repeating Non-conformity Correction	350 Euro	FLAT (Per each repeating non-conformity review)	The contract will include a one-time review of the non-conformities. For repeating non-conformity reviews within a defined deadline will be invoiced separately. Repeating reviews will not be conducted once the deadlines are reached.

G) FEE CALCULATION PARAMETERS

Type of Assessment	Application Fee	Annual Certificate Usage Fee	Audit Fee	Technical Documentation Review Fee
Initial Assessment	+	+	+	+
Surveillance Assessment	-	+	+	+
Re-Assessment	+	+	+	+
Transfer Assessment (From another Notified Body to MCA)	+	+	+	o
Transfer Assessment (From MCA to another Notified Body)	***	-	-	-
Change Assessment	**	-	o	o
Scope Extension Assessment	+	*	o	o
Unannounced Site Audit	-	-	+	-
Follow-Up Audit	-	-	+	-

'o': *Optional* ***'+':*** *to be calculated* ***'-':*** *not to be calculated.*

* *For higher product classes*

** *The application fees to be invoiced for change assessment are given in section E.*

*** *The expenses to be invoiced for administrative work in case of a transfer from MCA to another notified body is 500 EUR.*

H) SPECIAL CONDITIONS FOR MANUFACTURERS BELONGING TO SMEs AS DEFINED IN RECOMMENDATION 2003/361/EC

%3 of discount is applied for SMEs from the total initial and re-certification contract amount.

İ) HOW TO CALCULATE AUDIT DURATION

Effective Number of Employees	Total Duration (man/day)
1-5	3
6-10	4
11-15	4,5
16-25	5
26-45	6
46-65	7
66-85	8

Refer to IAF MD-9 for a greater number of effective employees

Once the total audit duration is calculated, 1/3 will be allocated to surveillance audits and 2/3 to re-certification audits. For unannounced audits, the audit duration is 2 man/days.

J) HOW TO CALCULATE TECHNICAL DOCUMENTATION REVIEW DURATION

Normal Clinical Evaluation Duration		3 man/day				
Type	**Code**	**Normal**	**If systems (man/day)**	**If systems cover more than 5 devices (man/day)**	**If WET**	**If similar devices are combined under similar intended use**
Active (Diagnostic)	MDA0201-0204	3	5	+2	N/A	+2 For TD Review +1 For Clinical
Active (Therapeutic)	MDA0301-0318	3	5	+2	N/A	+2 For TD Review +1 For Clinical
Implantable	MDN1101-1104	4	6	+2	-1	+2 For TD Review +1 For Clinical
Non-Implantable	MDN1201-1214	3	6	+2	N/A	+2 For TD Review +1 For Clinical
Notes **1-** Systems: Systems consist of several components, which are medical devices on their own right; however, it requires every component of the system to be reviewed at the same time.						

Additional Conditions Applicable for Class IIa and Higher Devices (Applies together with the above table)

Condition	**Type/Code**	**Result**	**Remarks**
Class IIb active device administering/removing medicinal products	Rule 12	+1 man/day	Not whole rule 12 class IIb devices
Sterile Devices	MDS1005	+0,5 man/day per sterilization type	N/A
Devices requiring biocompatibility review	N/A	+1 man/day	N/A
Software	MDS1009	+1 man/day	N/A
Locally dispersed absorbed or biological coating	MDS1008	+1 man/day	Is not applicable if the device is systemically absorbed
Machinery	MDS1004	+0,5 man/day	N/A
CECP- For new class III and rule 12 devices	Article 54	+2 man/day	Only for new devices

Medicinal product consultation	Rule 14	+2 man/day per medicinal product	N/A
Devices that are systemically absorbed	Rule 21	+2 man/day per substance	N/A
New devices with pre-market clinical investigation	N/A	+2 man/day	Not applicable for legacy devices and devices with PMCF investigation
Orphan Devices	N/A	+2 man/day	N/A
Nanomaterial	MDS1007	+1 man/day	N/A
Annex XVI Devices	N/A	+1 man/day	N/A

Fixed Technical Documentation Review Durations for Class Is, Im, Ir Devices

Type	Duration (man/day)
Class Is	2
Class Im	2
Class Ir	2

Fixed Technical Documentation Review Durations for Sterile Systems/Procedure Packs

Normal Duration	If large range of diverse devices covered	If more than 1 sterilization type
2 man/day	4 man/day	+1 man/day per additional sterilization type

For surveillance review of Technical Documentation 0,5 to 1 day review may be applicable for certain devices and conditions.

K) PRICING CALCULATION EXAMPLE

Scenario 1

Product Name: Surgical Instrument (Class Ir), Surgical Instrument Bone Cutting System (Class IIa), Plate and Screw System (Class IIb Implant)

Product Count: 3

Product MDA/MDN Code: MDN1208, MDN1102

Number of Employees: 86

Sampling Applied: No

Critical Supplier: 2

Clinical Evaluation Assessment: Yes

Biocompatibility Review: Yes

Sterilization Review: N/A

Applied Increasing Factors For QMS Audit Duration: Critical Supplier +1 M/D

Applied Decreasing Factors For QMS Audit Duration: The company is already certified -%15

FEE FOR INITIAL CERTIFICATION

Application Fee	1000 EUR
QMS Audit Fee	9,5 M/D X 2500 EUR
TD Review Fee	20,5 M/D X 2500 EUR
Annual Certificate Usage Fee	11000 EUR
Total	88500EUR

FEE FOR SURVEILLANCE

QMS Audit Fee	3 M/D X 2500 EUR
TD Review Fee	1,5 M/D X 2500 EUR
Annual Certificate Usage Fee	11000 EUR
Total	33500 EUR

FEE FOR UNANNOUNCED AUDIT

QMS Audit Fee	2 M/D X 2500 EUR
Total	5000 EUR

Scenario 2

Product Name: Feeding Catheter (Class IIa), Nasogastric Catheter (Class IIa), Nelaton Catheter (Class IIa)

Product Count: 3

Product MDA/MDN Code: MDN1202

Number of Employee: 16

Sampling Applied: Yes

Clinical Evaluation Assessment: Yes

Biocompatibility Review: Yes

Sterilization Review: Yes

Critical Supplier: 0

Applied Increasing Factors For QMS Audit Duration: Sterilization +0,5 M/D

Applied Decreasing Factors For QMS Audit Duration: Low risk product -%15

FEE FOR INITIAL CERTIFICATION (Sampling- Feeding Catheter (Class IIa))

Application Fee	1500 EUR
QMS Audit Fee	5 M/D X 2500 EUR
TD Review Fee	7,5 M/D X 2500 EUR
Annual Certificate Usage Fee	7000 EUR
Total	39750 EUR

FEE FOR SURVEILLANCE 1 (Sampling- Nasogastric Catheter (Class IIa))

QMS Audit Fee	1,5 M/D X 2500 EUR
TD Review Fee	7,5 M/D X 2500 EUR
Annual Certificate Usage Fee	7000 EUR
Total	29500 EUR

FEE FOR SURVEILLANCE 2 (Sampling- Nelaton Catheter (Class IIa))

QMS Audit Fee	1,5 M/D X 2500 EUR
TD Review Fee	8 M/D X 2500 EUR
Annual Certificate Usage Fee	7000 EUR
Total	30750 EUR

FEE FOR UNANNOUNCED AUDIT

QMS Audit Fee	2 M/D X 2500 EUR
Total	5000 EUR

Scenario 3

Product Name: Medical Device Disinfectant (Class IIb), Medical Device Disinfectant (Class IIa), Hemodialysis solutions and concentrates (Class IIb), Endoscope Washer and Disinfector Device (Class IIb)

Product Count: 4

Product MDA/MDN Code: MDN1211, MDN 1202, MDA0317

Number of Employee: 45

Sampling Applied: No

Clinical Evaluation Assessment: Yes

Biocompatibility Review: N/A

Sterilization Review: N/A

Machinery (MDS 1004): Yes

Applied Increasing Factors For QMS Audit Duration: Requiring interpreter(s) +%10, Require visiting temporary sites +0,5 M/D, Number of MDA and MDN codes categories included +%10

Applied Decreasing Factors For QMS Audit Duration: Maturity of the management system -%20

FEE FOR INITIAL CERTIFICATION

Application Fee	2000 EUR
QMS Audit Fee	6,5 M/D X 2500 EUR
TD Review Fee	28,5 M/D X 2500 EUR
Annual Certificate Usage Fee	9000 EUR
Total	97250 EUR

FEE FOR SURVEILLANCE

QMS Audit Fee	2 M/D X 2500 EUR
TD Review Fee	2 M/D X 2500 EUR
Annual Certificate Usage Fee	9000 EUR
Total	19000 EUR

FEE FOR UNANNOUNCED AUDIT

QMS Audit Fee	2 M/D X 2500 EUR
Total	5000 EUR

Scenario 4

Product Name: Dental implant (Class IIb Implantable), Surgical Instrument Set (Class IIa)

Product Count: 2

Product MDA/MDN Code: MDN1103, MDN 1208

Number of Employee: 175

Sampling Applied: No

Clinical Evaluation Assessment: Yes

Biocompatibility Review: Yes

Sterilization Review: Yes

Applied Increasing Factors For QMS Audit Duration: Critical Supplier +0,5 M/D, Sterilization +0,5 M/D, Highly complex processes +%10

Applied Decreasing Factors For QMS Audit Duration: Company is already certified -%15

FEE FOR INITIAL CERTIFICATION

Application Fee	2500 EUR
QMS Audit Fee	11,5 M/D X 2500 EUR
TD Review Fee	15,5 M/D X 2500 EUR
Annual Certificate Usage Fee	11000 EUR
Total	81000 EUR

FEE FOR SURVEILLANCE

QMS Audit Fee	4 M/D X 2500 EUR
TD Review Fee	1,5 M/D X 2500 EUR
Annual Certificate Usage Fee	11000 EUR
Total	24750 EUR

FEE FOR UNANNOUNCED AUDIT

QMS Audit Fee	2 M/D X 2500 EUR
Total	5000 EUR

Scenario 5

Product Name: Ablation Catheter (Class III)

Product Count: 1

Product MDA/MDN Code: MDN1104

Number of Employee: 10

Sampling Applied: No

Clinical Evaluation Assessment: Yes

Biocompatibility Review: Yes

Sterilization Review: Yes

Pre-Market Clinical Investigation Review For New Devices: Yes

Applied Increasing Factors For QMS Audit Duration: Audit scope including Class III devices +%10 M/D, Sterilization +0,5 M/D, Highly complex processes +%10

Applied Decreasing Factors For QMS Audit Duration: N/A

FEE FOR INITIAL CERTIFICATION

Application Fee	3500 EUR
QMS Audit Fee	5,5 M/D X 2500 EUR
TD Review Fee	11,5 M/D X 2500 EUR
Annual Certificate Usage Fee	15000 EUR
Total	61000 EUR

FEE FOR SURVEILLANCE

QMS Audit Fee	2 M/D X 2500 EUR
TD Review Fee	1 M/D X 2500 EUR
Annual Certificate Usage Fee	15000 EUR
Total	17250 EUR

FEE FOR UNANNOUNCED AUDIT

QMS Audit Fee	2 M/D X 2500 EUR
Total	5000 EUR

Scenario 6

Product Name: Antibacterial Absorbable Suture (Class III incorporating medicinal product), Absorbable Suture (Class III)

Product Count: 2

Product MDA/MDN Code: MDN1203

Number of Employee: 75

Clinical Evaluation Assessment: Yes

Clinical Evaluation Consultation Procedure (Article 54) CECP For new Class III and rule 12 devices: Yes

Competent Authority Medicinal Product Consultation: Yes

Pre-Market Clinical Investigation Review For New Devices: Yes

Absorbable-Locally Dispersed-Biological Coating Product Review: Yes

Applied Increasing Factors For QMS Audit Duration: Audit scope including Class III devices +%10 M/D, Sterilization +0,5 M/D, Critical Supplier +0,5 M/D

Applied Decreasing Factors For QMS Audit Duration: N/A

FEE FOR INITIAL CERTIFICATION

Application Fee	4000 EUR

QMS Audit Fee	10 M/D X 2500 EUR
TD Review Fee	34 M/D X 2500 EUR
Annual Certificate Usage Fee	17000 EUR
Total	131000 EUR

FEE FOR SURVEILLANCE

QMS Audit Fee	3,5 M/D X 2500 EUR
TD Review Fee	2 M/D X 2500 EUR
Annual Certificate Usage Fee	17000 EUR
Total	30750 EUR

FEE FOR UNANNOUNCED AUDIT

QMS Audit Fee	2 M/D X 2500 EUR
Total	5000 EUR