Pricelist for conformity assessment activities on medical devices
According to regulation (EU) 2017/745

List of Standard Fees for Conformity Assessment Activities under the MDR (2017/745) valid for the following Notified Bodies:

- Kiwa Cermet Italia SpA - NB0476
- Kiwa Assurance BV - NB1912
- Kiwa Belgelendirme Hizmetleri A.Ş. – NB1984

Service	Type of Fee	Fee in local currency	Factors influencing the calculation of fee charged[1]	Fee range (min- max)
Administrative charges				
Fee for application (initial and recertification)	Flat	3.300 €	\	\
Fee for Change of Certification/Notification	Flat	800 €	\	\
Fee for Extension of certification	Flat	1.500 €	\	\
Fee for Annual maintenance	Flat	SME[2]: 1.500 € Non-SME: 1.750 €	Companies belonging to SME	\
Fee for Travel time (excluding costs for travel and lodging)	Hourly	150 € - 160 €	different currencies and travel policies that may apply to some specific geographies; each time spent to reach the Manufacturer/supplier's premises from the starting point of the auditors	\
Fee related to handling of external consultations with the competent authorities (CAs) for medicinal product and device utilizing animal tissue	Flat	15% of the consultation' cost charged by CA	The choice of the CA	According to specific CA 'pricelist
Fee related to handling of external consultations with the Expert Panel (EP)	Hourly	400 €	Number of devices (Basic-UDI-DI) subjected to EP' opinion	Minimum 1.600 € for each Basic-UDI-DI

[1] This list does not claim to be exhaustive

[2] As defined in Recommendation 2003/361/EC; the fulfilment of the criteria of SME status has to be demonstrated by Manufacturer trough specific documentation/information

Service	Type of Fee	Fee in local currency	Factors influencing the calculation of fee charged[1]	Fee range (min- max)
Fee related to handling of external laboratory tests	Flat	15% of the test' cost charged by laboratory	The choice of the laboratories	\
Re-issue of digital EU certificate, issue of hard EU certificate or duplicates or certified copies	Flat	€ 350,00	Number of certificates requested	Minimum 350 € for each certificate
Non-standard or legalized/apostilled trough Embassy or authenticated by notary EU certificate	Flat	At costs charged by Embassy/Notary	\	\
Fee related to handling non-standard or legalized/apostilled or authenticated EU certificate	Flat	15% of the cost to produce or legalized certificate	Types and number of certificates requested	\
Auditing charges				
Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Hourly	310 €	Size of the company, the number of FTEs and work shifts, the complexity of the company's processes, the sites audited, including those of critical suppliers; furthermore, the substantial deficiency of the QMS and the number of non-conformities raised may influence the total number of man-days[3]	Minimum 3 man-days = 7.440 €
Unannounced Audit	Daily[4]	5.600 – 8.500	Different currencies and specific geographies between NB, the number of devices to be sampled, the number of vigilance cases and deficiencies to QMS	\

[3] Man-days are composed by 8 hours per day. Man-days for Audit are calculated based on IAF MD9 guidelines. Man-days for documentation review are calculated according internal procedures of each NB.

[4] Daily means at least one day with 1 auditor and 1 assessor

Service	Type of Fee	Fee in local currency	Factors influencing the calculation of fee charged[1]	Fee range (min- max)
Reporting (if not covered above)	Hourly	310 €	\	\
Product testing charges				
Documentation Review charges				
Technical documentation assessment	Hourly	400 €	the class of MD, the type (e.g., Implantable, animal tissue, medicinal product) and technology, its complexity and number of variants may influence the number of man-days[5]; furthermore, the quality and completeness of the technical documentation, the number of nonconformities raised may influence the number of subsequent rounds of reviews needed	Minimum per device per risk class: Is/m/r = 4.800 € IIa = 9.600 € IIb = 12.800 € III = 19.200 €
Clinical data evaluation premarket and post market	Hourly	400 €		Minimum per device and risk class: IIa = 4.800 € IIb = 8.000 € III = 11.200 €
Evaluation/review of the Periodic Safety Update Report (PSUR) / Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	400 €	Number of PSUR/SSCP and MD included per each document	Minimum per device: 3.200 €
Reporting (if not covered above)	Hourly	400 €	\	\
Reporting on specific documentation required by competent authorities (MDR, Annex IX 5.2, 5.3.2 5.4 (b)) or by Expert Panel (MDR art. 54.1, Annex IX 5.1) to prepare the application relating to external consultations	Hourly	400 €	Number of devices (Basic-UDI) subjected to application for consultation	Minimum per device Medicinal product = 9.600 Containing animal tissue or

[5] Same as footnote 3

Service	Type of Fee	Fee in local currency	Factors influencing the calculation of fee charged[1]	Fee range (min- max)
				belong to art 54.1 = 3.200 €
Other				
Discount may be applicable, based on the countries discount policies.				
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC	The number of audit days are lower based on the FTE of the manufacturer (calculated according on IAF MD9 guidelines). Annual maintenance fee is lower for SMEs Based on country discount policy additional discount may be applied			