

**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	North-West Europe, UK, Canada & US	Middle & South Europe	Turkey & rest of the world	Factors influencing the calculation of fee charged <sup>1</sup>	Fee range (min- max)
<b>Administrative charges</b>						
Fee for application (initial and recertification)	Flat	3.300 €	3.300 €	3.300 €	\	\
Fee for Notification of Change	Flat	830 €	830 €	830 €	\	\
Fee for Notification of Extension	Flat	2.200 €	2.200 €	2.200 €	\	\
Fee for Annual maintenance	Flat	SME <sup>2</sup> : 1.700 € Non-SME: 1.950 €	SME <sup>2</sup> : 1.700 € Non-SME: 1.950 €	SME <sup>3</sup> : 1.700 € Non-SME: 1.950 €	SME <sup>2</sup> : 1.700 € Non-SME: 1.950 €	\
Fee for Travel time (excluding costs for travel and lodging)	Hourly	160 €	150 € - 160 €	150 € - 160 €	different currencies and travel policies that may apply to some specific geographies; each time	\

<sup>1</sup> This list does not claim to be exhaustive

<sup>2</sup> As defined in Recommendation 2003/361/EC; the fulfilment of the criteria of SME status has to be demonstrated by Manufacturer through specific documentation/information

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					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	15% of the consultation' cost charged by CA	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	415 €	400 €	400 €	Number of devices (Basic-UDI-DI) subjected to EP' opinion	Minimum 1.600 € for each Basic-UDI-DI
Fee related to handling of external laboratory tests	Flat	15% of the test' cost charged by laboratory	15% of the test' cost charged by laboratory	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 €	350 €	350 €	Number of certificates requested	Minimum 350 € for each certificate
Issue of amended/ extension EU certificate	Flat	830 €- 2.200 €	830 €- 2.200 €	830 €- 2.200 €		830 €- 2.200€
Non-standard or legalized/apostilled trough Embassy or authenticated by notary EU certificate	Flat	At costs charged by Embassy/Notary	At costs charged by Embassy/Notary	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	15% of the cost to produce or legalized	15% of the cost to produce or legalized	Types and number of certificates requested	\

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		certificate	certificate	certificate		
<b>Auditing charges</b>						
Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Hourly	310 €	310 €	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 <sup>4</sup>	Minimum 3 man-days
Unannounced Audit	Daily <sup>5</sup>	5.600 – 8.500	5.600 – 8.500	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	\
Reporting (if not covered above)	Hourly	310 €	310 €	310 €	\	\
<b>Product testing charges</b>						
Annex X testing	Hourly	415 €	415 €	415 €		

<sup>4</sup> 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.

<sup>5</sup> Daily means at least one day with 1 auditor and 1 assessor

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<b>Documentation Review charges</b>						
Technical documentation assessment	Hourly	415 €	400 €	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 <sup>6</sup> ; 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	415 €	400 €	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	415 €	400 €	400 €	Number of PSUR/SSCP and MD included per each document	Minimum per device: 3.200 €
Handling of vigilance cases	Hourly	415 €	400 €	400 €	\	\
Reporting (if not covered above)	Hourly	415 €			Number of devices	Minimum per

<sup>6</sup> Same as footnote 3

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& 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			400 €	400 €	(Basic-UDI) subjected to application for consultation	device Medicinal product = 9.600 Containing animal tissue or belong to art 54.1 = 3.200 €
<b>Other</b>						
<i>Applicable up from January 1, 2026</i> <i>Discount may be applicable, based on discount policies.</i>						
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 SME's. Based on discount policies additional discount may be applied.		