List of Standard Fees for Conformity Assessments Activities under the MDR (2017/745)

Notified Body DEKRA Certification B.V. (NB 0344)

	Type of Fee	Fee in local currency	Factors influencing the calculation of fee charged	Expected fee range (min-max). In special cases fees can differ
Administrative charges				
Application fee	Flat	€ 1.800	Complexity of the applications, number of applications	≥ € 1.800
Administrative fee related to changes	Hourly	€ 450	Complexity of the change	≥ € 450
Annual certificate maintenance fee	Flat	€ 2.340	First certificate - costs for regulatory requirements that apply to the accreditations as an auditing organization	€ 2.340
		€ 1.300	Per additional certificate - costs for regulatory requirements that apply to the accreditations as an auditing organization	€ 1.300
Travel time costs	Hourly	€ 162	Location of manufacturer	€ 162 - € 1.296 (per hour - day)
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Hourly	€ 450	Testing or consultations by third party is billed at cost	≥ € 450
Auditing				
Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier) (including reporting and project management & excluding travel time and expenses).	Hourly	€ 306	Number of FTE's, increase/decrease factors (MD9)	€ 2.450 - € 4.900 (per 0,5 – 1 day)
Unannounced Audit	Daily	€ 3.615	Audit tariff per day, preparation and reporting	€ 3.615 - € 7.230
Product testing				
Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	Hourly	€ 450	Dependent on complexity of the product(s)	≥ € 450, plus costs incurred for external testing will be invoiced at cost

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Documentation review				
Technical documentation assessment Including Project management and certification management	Hourly	€ 450	Dependent on risk classification/complexity of the submitted file(s)	€ 3.600 - € 72.000 (1-20 days)
Clinical evaluation report assessment (CEAR)	Hourly	€ 450	Part of the technical documentation assessment and related project management	See Technical documentation assessment above
Expert panel consultation	Hourly	€ 450	Part of the technical documentation assessment and related project management	See Technical documentation assessment above
Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	€ 450	Dependent on complexity of the submitted file(s). Part of the PSUR report	See Evaluation/review of the Periodic Safety Update Report below
Consultation with medicinal product authorities	Hourly	€ 450	Dependent on complexity of the submitted file(s)	≥ € 450, plus costs incurred for external consultation will be invoiced at cost
Consultation with human tissue and cells competent authority	Hourly	€ 450	Dependent on complexity of the submitted file(s)	≥ € 450, plus costs incurred for external consultation will be invoiced at cost
Consultation with the coordinating competent authority for devices utilizing animal tissues	Hourly	€ 450	Dependent on complexity of the submitted file(s)	≥ € 450, plus costs incurred for external consultation will be invoiced at cost
Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	€ 450	Dependent on complexity of the submitted file(s)	€ 3.600 – € 7.200 (1 – 2 days)
Assessment of changes	Hourly	€ 450	Dependent on complexity of the submitted file(s)	≥ € 450

Disclaimers:

Expected fee range might differ due to the complexity of the dossier(s). Reporting is covered in the tariffs shown above. Special considerations are given to manufacturers that are part of SMEs through the audit calculation which is dependent on the number of full-time equivalents (FTEs). SMEs will thus (in general) have fewer audit days. Please note that the information provided is indicative and does not confer any rights. It is not tailored to your specific circumstances. For detailed information and an accurate quotation, we encourage you to contact us and request a formal proposal for our services.

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For questions about our services, please contact medical.nl@dekra.com or call +31(0)88 96 83005.
Find out more about how DEKRA can support you by visiting our website.

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