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	Flat	€ 395	Complexity of the change	≥ € 395
Annual certificate maintenance fee	Flat	€ 2.300	First certificate - costs for regulatory requirements that apply to the accreditations as an auditing organization	€ 2.300
		€ 1.280	Per additional certificate - costs for regulatory requirements that apply to the accreditations as an auditing organization	€ 1.280
Travel time costs	Hourly	€ 160	Location of manufacturer	€ 160 - € 1.920 (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)	Hourly	€ 320	Number of FTE's, increase/decrease factors (MD9), reporting and project management	≥ 320
Unannounced Audit	Daily	€ 3.560	Audit tariff per day, preparation and reporting	€ 3.560 - € 7.120
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

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
Documentation review				
Technical documentation assessment	Hourly	€ 450	Dependent on risk classification/complexity of the submitted file(s). Project management and certification management	€ 3.600 (day) (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)	≥ € 450
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)	≥ € 450
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. In cases where the manufacturer's location allows the use of local auditors or technical experts, fees may be invoiced in local currency and could vary. Prices in other currencies can be provided upon request.

DEKRA Certification B.V.
Meander 1051
6825 MJ Arnhem

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.