

DEKRA Certification B.V. Service Fees 2023 under the MDR (2017/745) & IVDR (2017/746)

Audit fees*	Quantity	Fee
MDR / IVDR and / or MDSAP Audit or any combination audit entailing these scheme(s) Audit tariff including reporting (25%) and project management (25%)	per hour	€ 290
Unannounced Audit Audit tariff including preparation and reporting (20%)	per day (2 auditors)	€ 6.870

^{*}Excluded are any costs related to (if necessary) sample collection and / or additional testing.

Other Service fees	Quantity	Fee
Technical documentation assessment	per hour	€ 430

Travel fees	Quantity	Fee
Travel time	per hour from Arnhem	€ 155
Kilometer rate	per kilometer from Arnhem	€ 0,65
Travel and subsistence expenses	per audit event	billed at cost

Additional DEKRA Certification B.V. services

DEKRA is an accredited body (0344) and international recognized registrar for several Medical Device certification schemes:

CE (EU) Certification and prolongation of certification according to the Medical Device Regulation (2017/745),

Medical Device Directive (MDD) 93/42/EEC; the Active Implantable Medical Device Directive (AIMD) 90/385/EEC, the In-vitro Diagnostics Medical Device Directive (IVDD) 98/79/EC and

In Vitro-Diagnostic Device Regulation 2017/746 (IVDR)

MDSAP Medical Device Single Audit Program: US, Canada, Japan, Brazil and Australia

Taiwan Technical Cooperation Program

Find out how DEKRA can support you. Visit: Medical Device Regulatory Services | DEKRA