

LIST OF STANDARD FEES – MDR, IVDR			
Administrative charges	Type of Fee	Factors influencing the calculation of fee charged	Fee range (min - max)
Application fee	Flat	FTE of the company	3500 € - 7500 €
Annual certificate maintenance fee	Flat	FTE of the company	2200 € - 4300 €
Travel time and travel costs	Flat	Distance from NB office in Finland	820 € - 6500 € (include all travel costs)
Auditing	Type of Fee	Factors influencing the calculation of fee charged	Fee range (min - max)
Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Daily	FTE of the company (audit length)	2 560 €
Unannounced Audit	Daily	FTE of the company (audit length)	2560 €
Audit reporting	Flat	N/A	5120 €
Documentation Review	Type of Fee	Factors influencing the calculation of fee charged	Fee range (min - max)
Technical documentation assessment	Hourly	Device classification; Actual time spent for the assessment; Maturity of the provided documentation	320 €
Clinical evaluation report assessment (CEAR)	Hourly	-''-	320 €
Fee charged for conducting consultations with the expert panels / EU reference laboratories	Hourly	Actual time spent for the assessment; Maturity of the provided documentation	320 €
Batch verification of manufactured class D IVDs	Hourly	-''-	320 €
Validation of the Summary of Safety and Clinical Performance (SSCP)	Hourly	-''-	320 €
Validation of the Summary of Safety and Performance (SSP)	Hourly	-''-	320 €
Evaluation/review of the Periodic Safety Update Report (PSUR)	Hourly	-''-	320 € (MDR Article 86(2); IVDR Article 81(2))
Assessment of changes	Hourly	Type of change; Actual time spent for the assessment	320 €
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC	Audit days, application and annual certificate maintenance fees are dependent on the FTE of the manufacturer.		