

2023 MDR LIST OF STANDARD FEES*

Validity of the fees

- The fees come into effect from date of 01. Jan.2023 and ends 31. Dec.2023.
- All prices indicated in this pricelist are in Swedish Krona (SEK).
- Contact your local office for country specific pricing. Country specific pricing is only available for North America, India and China.

	COST (INCLUDES ALL PLANNING and REPORTING, EXCLUDES TRAVEL COSTS)
Full day audit	41 000
Half day audit	32 500

Technical Documentation Sampling and Assessment

TD COMPLEXITY	COST
Basic Technical Documentation (all classes)	157 000
Addition for Active device	20 000
Addition for Devices with software (applicable for standalone SW also)	20 000
Addition for Sterile device (per method. Also for devices to be sterilized)	20 000
Addition for (non-surgical) Invasive device (excluding sterile)	20 000
Addition for Surgical invasive device (excluding sterile)	31 000
Addition for Implant or class III (both invasive and one sterile code included)	92 000

The above costs, for Technical Documentation assessment, include **only a first assessment** of the documentation. If non-conformities are identified, management of these will add to the total cost on a running basis.

After the first round, any additional rounds will be charged at an hourly rate of:

	COST
Technical Documentation Assessor	4 000 / hour
Clinician	5 500 / hour

Complete pricelist

The complete pricelist covers more detailed information and will be provided during the formal application.

