Required documents shall preferably be submitted electronically, in the way that the numbering can directly be assigned to the relevant documents. For submission the Deutsche Akkreditierungsstelle GmbH (DAkkS) provides a **structured zip-folder** where the required documents should be stored electronically and resend to the case manager. In individual cases documents must be submitted in hard copy. The case manager will inform you accordingly.

All documents/evidences must be submitted[1] before the assessment in due time[2]. By sending the documents the CAB ensures DAkkS the completeness of the submitted documents. If necessary, further documents may be required by the case manager or the assigned assessor.

Documents must be submitted in German or English language.

No.	Documents
1.	**Complete** documentation of the management system of the medical laboratory and of the granted/applied scope of accreditation (quality management manual, procedures, work instructions or other specifications with regard to the applied/accredited examination schemes)
2.	List of all quality management (QM) documents (including version and/or date of validity)
3.	Zuletzt durchgeführte Managementbewertung
4.	List of services and specimen samples of all used specification schedules
5.	Evidence of organisational structure, ownership and legal form of the medical laboratory (trade register excerpt, list of shareholders, organisation chart(s)) *If the laboratory is part of an organisation (within the legal entity or within a larger corporate structure) the ownership structure, the integration within the organisation and the relations to other organisational units must be submitted with appropriate information (e. g. with detailed organisational charts and lists of shareholders of all sub-organisations)* Evidences about structure, ownership and legal structure of the integrated legal entities as well as information about further accreditations of these legal entities must be submitted.
6.	Risk analysis and liability estimation for the calculation of an appropriate level of insurance and evidence of a liability insurance or an equivalent solution (especially for financial loss). Information on scopes with a statutory insurance obligation.
7.	List of employees stating their qualification/professional training/responsibilities at all levels of the activity of the medical laboratory
8.	List of existing contractual regulations with external personnel (e. g. external consultants), contractors (sub-contractors) and other cooperation partners as far as involved in the conformity assessment activities as well as samples of relevant contracts.
9.	Explanation on used IT-systems and their function and a description of interfaces between those IT-systems as well as to external databases/archive systems including the process of release of those systems.
10.	Sample of a report (without patient data) for each examination field applied for accreditation

[1] To submit documents incomplete or late can be punished as an administrative offence according to § 12 AkkStellG (Accreditation Body Act)

[2] The assessment for initial accreditation of the medical laboratory will be scheduled not before the required documents are submitted completely. In case of surveillance, extension of accreditation or reaccreditation documents shall be submitted at least 6 weeks before the scheduled assessment.

No.	Documents
11.	List of all performed proficiency tests (and interlaboratory comparisons) of the last 3 years, incl. interpretation (if applicable of single parameters or measurands). Certificates of proficiency tests do not need to be submitted.
12.	Metrological traceability: List of equipment with in-house registration (including used rental equipment, used working standards as well as equipment/facilities which are not under permanent control of the CAB). **Nesessary information:** Unique identification, location, measurand (of which an evidence of the metrological traceability must be available), name of the equipment/type of equipment/object, producer, calibration-/functional checks interval, identification/name of the evidence(s) regarding metrological traceability, **type of measurement traceability (regarding 71 SD 0 005_e).** *Optional specifications: Testing standard, serial number, responsible person for the equipment, and others*
13.	Spatial plan indicating the examination areas including information on the use of mobile facilities for examination activities
14.	Last annual report with information on/data of the medical laboratory and performed certification activities *The template to be filled in is included in the zip-folder.* *Document will be submitted to DAkkS electronically (Excel-document).*
15.	Filled Partial Assessment Report/Checklist DIN EN ISO 15189 *The template to be filled in is included in the zip-folder.* *Document will be submitted to DAkkS electronically (Word-document).*
16.	Excel-file with the applied scope of accreditation (FO-Antrag GB_ML_Diagnostik) for initial accreditation **or** Excel-file annex to the Accreditation Certificate for surveillance/ extension/ reaccreditation **and** the current list of all examination procedures in the scope of accreditation (if different from the annex of the accreditation certificate).

No.	Documents
17.	**Normative documents within the scope of accreditation** [3] Submission of a copy of all certificate-relevant technical standards or standards for the activities of the medical laboratory in the accredited area, as far as DAkkS does not determine a different regulation. All standards, documents equivalent to standards, in-house methods, etc., which are applied for accreditation or belong to the scope of accreditation and contain requirements for the performance of testing activities, as well as other documents which are or shall be listed in the annex to the certificate, and all the above-mentioned documents which are offered to the customers of the medical laboratory as an "accredited service" within the scope of an existing accreditation with flexible scope shall be submitted[4]. (The provision is permitted license-free according to § 45 Copyright Act (§45 Urheberrechtsgesetz (UrhG)) *These documents will be send separately from the other listed documents in a separate zip-folder. The identification of the normative documents is contained in the respective file name. If the normative documents within the scope of accreditation have already been submitted by the medical laboratory, only the normative documents concerning changes of the scope shall be submitted.*

[3] If the relevant documents have already been submitted in full under point 1 of the list (SOPs, work instructions), no documents are required

[4] Publicly freely accessible documents that are the subject of the accreditation scope do not have to be submitted.