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 DAkkS. In individual cases it may be necessary to submit in hard copy.

All documents/evidences must be submitted[1] immediately after request[2]. By sending the documents the CAB ensures DAkkS the completeness of the submitted documents. If necessary, further documents may be required by DAkkS 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.	Most recent management review with contents according to DIN EN ISO 15189:2014 section 4.15.2 or according to DIN EN ISO 15189:2023 section 8.9.2
4.	Scope of accreditation (Excel file FO-Antrag GB_ML_Diagnostik) for **initial accreditation** Updated "annex to the Accreditation Certificate" for **extension/change** Current list of all examination procedures within the scope of accreditation for **surveillance, reassessment and extension/change** For testing laboratories with a flexible scope: A current list of all applied testing methods within the flexible scope of accreditation (incl. the marking of the last changes)
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)*
6.	Coverage of existing liability risks, e. g. evidence of a liability insurance including information about the scope of insurance (liability and financial loss) or information on an equivalent solution.
7.	Current information about the number of employees[3] for all activities of the medical laboratory broken down according to their function[4], working area[5]and the contractual binding[6] to the laboratory as well as model contracts for external employees

[1] The planning of the assessment for initial accreditation or extension of the medical laboratory takes place immediately after confirmation of the application. The documents are requested with this confirmation and must be submitted immediately. If no documents are submitted, the application will be rejected.
Documents for surveillance and reassessment must be submitted immediately upon request

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

[3] Regardless of the extent of employment, each employee counts.

[4] e. g. medial doctors/academics, technical employees, non-technical and administrative employees.

[5] e. g. according to locations and/or concrete working areas (e. g. examination areas) of the laboratory.

[6] Permanent employees (internal) and further employees bound by contract (external).

No.	Documents
8.	List of contractors (contracting laboratories) and other cooperation partners (e. g. transport services, cleaning companies, IT-services, service companies) as far as involved in the conformity assessment activities as well as relevant model contracts
9.	List of services and specimen samples of all used specification schedules
10.	Evidence of the obligation of the laboratories top management regarding the impartiality according to DIN EN ISO 15189:2023 section 4.1
11.	Analysis of risks to impartiality, including analysis of related entities and presentation of the management of impartiality according to DIN EN ISO 15189:2023 section 4.1
12.	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
13.	Sample of a report (without patient data) for each examination field applied for accreditation
14.	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*
15.	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). **Necessary 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*
16.	Spatial plan indicating the examination areas including information on the use of mobile facilities for examination activities
17.	Filled Partial Assessment Report/Checklist DIN EN ISO 15189:2023, where required filled checklist for additional requirements for Point-of-Care Testing (POCT) *The template to be filled in is included in the ZIP-folder.* *Document will be submitted to DAkkS electronically (Word-document).*
18.	Overview of changes that occur within norm conversion

No.	Documents
19.	**Normative documents within the scope of accreditation** [7] Submission of a copy of all certificate-relevant specification (e. g. work instructions, 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 instructions to in-house methods, CE-marked-procedures, and, if applicable, all standards, documents equivalent to standards, , etc., which are applied for accreditation or belong to the scope of accreditation and contain requirements for the performance of examination 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[8]. (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 part of 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.*

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

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