**Ansøgning om DANAKs evaluering af ordning/scheme, jf. AB 21**

Nedenstående skema er udarbejdet ud fra kravene i EA-1/22. Nogle af kravene fra EA 1/22 har EA anført i en formular, mens andre krav alene er anført i anneks 1 og 2 til EA-1/22. DANAK har samlet kravene i denne blanket. Tekst på dansk med kursiv er hjælpetekst tilføjet af DANAK.

Vejledning til udfyldelse fremgår af EA-1/22, som kan findes [her](https://european-accreditation.org/publications/ea-1-22-a/).

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| **Basisoplysninger om ordningen og ordningsejer** (jf. EA-formular) | **Ordningsejers svar** | **DANAKs bedømmelse** |
| **Conformity Assessment Scheme**Name of the scheme – Version date |  |  |
| **Scheme Owner (SO)**Name and acronym, web address |  |  |
| **Subject of assessment** *Kort beskrivelse, der uddybes i pkt. 12 nedenfor* |  |  |
| **Normative documents** |  |  |
| **Conformity assessment methods** |  |  |
| **Conformity declaration** |  |  |
| **Relevant accreditation standard** *Begrundelse anføres i pkt. 5 nedenfor* | *Oplys fx produktcertificering 17065* |  |
| **Scheme Specific Requirements for NAB’s** *Beskrivelse anføres i pkt. 11 nedenfor* | *Vælg Ja eller nej* |  |

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| Forudsætning for godkendelse af ordning til akkreditering, (jf. EA-formular) | Ordningsejers vurdering Svar ja/nej og angiv reference til ordningens kravdokumenter | DANAKs bedømmelse |
| 3.1.1 The SO shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its activities. |  |  |
| 3.1.2 The SO has the authority to establish and change the requirements of the CAS. |  |  |
| 3.1.3. The SO shall have the mandate to cooperate with the NAB or hAB. |  |  |
| 3.1.4. The SO shall have a mechanism to provide for feedback from the NAB or hAB on the operation of the CAS. The monitoring of CABs by the SO does not exempt the SO from the above obligation.Note: Where for some reason (e.g. no accredited CABs anymore), the actual hAB is no longer willing to act as the hAB, the hAB will inform the SO and EA. It will be the responsibility of the SO to ask another NAB to take over the role as hAB. |  |  |
| 3.1.5. The SO shall be able to demonstrate that there is a need and support in the market for the CAS. This may include demonstration of added value, the involvement of interested parties, government initiatives or regulatory needs. The SO shall be able to provide evidence of market need and support for the CAS coming from relevant interested parties. Note: EA acknowledges that the number and nature of these “relevant interested parties” may be different for different CASs. Of particular relevance and importance in the demonstration of market need is the viewpoint of interested parties representing the CAS end-users (e.g. consumers or industry).  |  |  |
| 3.1.6. The SO shall commit to accept results from CABs accredited by any EA MLA signatory (for the relevant scope) which follows the requirements laid down in the CAS |  |  |
| 3.1.7.The SO shall demonstrate that the CAS has been validated. The validation shall be documented and include: * A description of the purpose of the CAS;
* A description of the requirements of the CAS;
* An analysis of the appropriateness of the established requirements for fulfilling the defined purpose of the CAS;
* A description of the methods to be used for determining fulfilment of the requirements;
* The identification of applicable requirements from other relevant standards used for conformity assessment. (e.g., test result from ISO/IEC 17025, claims’ from ISO/IEC 17029, Management system certification from ISO/IEC 17021-1.).
* An analysis of the appropriateness of the described methods to be used for determining fulfilment of the requirements;
* A decision on the conformity assessment activity to be used (including the identification of the applicable conformity assessment standard);
* An analysis of the appropriateness of the selected conformity assessment activity.

Note: validation might not be required in the case of evaluation of an existing (old) CAS which has been used for accredited conformity assessment purposes. – see 4.2.2.b Evaluation of a CAS operated before 21st of May 2015  |  |  |
| 3.1.8. The SO shall restrict the use of the CAS to accredited CABs with which an agreement has been entered into. Such an agreement must guarantee at least that the CABs will use the CAS as it is, without any limitations and without any additions. A transition arrangement should clarify how the transition from non-accredited conformity assessment will be managed and how new CABs may start using the CAS. |  |  |
| 3.1.9. The SO shall be responsible for keeping the hAB and CABs informed of any relevant information and developments relating to the CAS, including in particular any proposed change in requirements. |  |  |
| 3.1.10 The SO shall be prepared to pay for the costs of the evaluation of its CAS by the NAB or hAB. |  |  |
| 3.1.11 The SO shall commit in writing to comply with the evaluation procedure. |  |  |

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| Specifikke krav til ordningen, (jf. EA formular) | Ordningsejers svar | DANAKs bedømmelse |
| 3.2.1. The conformity assessment process described or chosen by the SO shall fall within the scope of one of the EA MLA Level 3 standards (see EA-1/06). |  |  |
| 3.2.2. Scheme specific requirements placed on CABs by the SO shall not contradict, or exclude, any of the requirements included in the standard referred to in 3.2.1. |  |  |
| 3.2.3. If a CAS places scheme specific requirements on NABs, they shall not contradict or exclude any of the requirements in ISO/IEC 17011, EU Regulation (EC) 765/2008 and, where applicable, EA mandatory documents and IAF or ILAC documents endorsed by EA as mandatory. Any requirements for NABs must be included in the CAS and shall not be enforced by MOU’s or other contractual agreements with (individual) NABsScheme specific requirements for NABs (see clause 2.4) for international CASs require specific endorsement by the EA HHC. If a national CAS intends to expand to become international, then any agreement with the NAB on additional requirements to ISO/IEC 17011 will be considered as Scheme specific requirements to NABs and will not automatically be binding on other NABs. These specific requirements will first need to be accepted and endorsed by the EA HHC. The EA secretariat will maintain an overview of additional requirements for all of the CASs that have been successfully evaluated according to EA-1/22. |  |  |
| 3.2.4. CASs in the voluntary sector shall neither contradict, nor simply be the fulfilment of, applicable legal requirements, unless it has been accepted by the competent authority(ies) and it does not create any confusion between the CAS and the duties of the competent authority(ies) (e.g. monitoring mechanism) or between the role of the CABs and that of the said authority(ies).  |  |  |

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| **Ordningsejers egen bedømmelse, del 1,** (jf. EA 1/22 A-AB: 2023, Annex 1) | **Ordningsejers svar** | **DANAKs bedømmelse** |
| Ordningen forventes anvendt (vælg en af følgende): a) kun nationalt i Danmark, b) i flere EA-lande, hvor DANAK skal være home-AB, c) internationalt, uden home-AB |  |  |
| 1. Is the Scheme Owner (**SO**) willing to use DANAK as the unique contact point for the evaluation of the Conformity Assessment Scheme (**CAS**)?
 | *Svar skal være ja, hvis mulighed a eller b er valgt ovenfor.* |  |
| 1. Is the CAS currently being used by Conformity Assessment Bodies (**CABs**) under accreditation from any of the EA members? If yes, please identify the accreditation body. If no but it has previously been reviewed by a National Accreditation Body (**NAB**), please provide details and outcome of the evaluation.
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| **2b.** For the evaluation of existing CASs (used by several AB’s and where one AB (home AB) is appointed to perform evaluation of the scheme) the SO shall identify all the EA NABs implementing the CAS and demonstrate to the home AB what measures have been taken so that the NABs currently accrediting CABs for the CAS perform the accreditation in a harmonized way. |  |  |
| 1. Provide a full description of the SO including:
	* + Name and acronym, *fremgår side 1*
		+ Type of legal entity, *fremgår side 1*
		+ Address and web address, *fremgår side 1*
		+ Members (if relevant) and membership rules,
		+ Brief history,
		+ Any other activities performed if relevant,
		+ Relations to or links with other organizations and the authorities, both at international and national levels, if any,

Technical area of activity, for example aerospace, electrical testing, food safety, etc.  |  |  |
| 1. Provide evidence of market need or support for the scheme.
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| 1. Under which conformity assessment standard(s) does the scheme operate? (For example, product certification, testing, etc.) Include the rationale for your choice and identify the scheme document where it is specified.
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| 1. Is the CAS intended to be used only at a national level? If no, please specify geographical area of acceptance, for example a few European countries, all of Europe or global.
 | Svar er givet af SO øverst i denne tabel | NA |
| 1. Has the SO established CAS specific requirements for the operation of CABs wishing to operate within the CAS? If yes, please describe the specific CAS requirements and identify the CAS documents where these are described. State also how such requirements are made publicly available.
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| 1. Does the SO (by itself or through another organization) perform any kind of assessment of the CAB? If yes, refer to the CAS document where it is described. Does the SO perform any other kind of activity to confirm recognition of CABs which wish to work within the scope of the CAS, beyond requiring that they are accredited to the CAS requirements? If so, describe the activity and identify the CAS document(s) where this is stated.
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| 1. If the answer to the first question under 8 is yes, does the SO request the NABs to accept or take into account such an assessment during the accreditation process? If yes, please identify the CAS document where this is described.
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| 1. Does the CAS request EA or EA members to cooperate with the SO on issues other than accreditation of CABs? If yes, specify the areas of cooperation required and refer to the CAS document where these are described.
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| 1. Has the SO established CAS specific requirements for the operation of NABs? If yes, please identify the CAS document where these are described and explain for each of them the reason why these specific requirements have been introducedin terms of the goal of each of them and of the expected added value.
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| 1. What is the object of conformity assessment? Please state as specifically as possible and submit a copy of the certificate containing the specific attestation.

(Objects of conformity assessment may be products, services, materials, claims, installations, processes, systems, persons.)  |  |  |
| 1. What are the specific requirements relating to the characteristics of the object of conformity assessment? Please identify the CAS documents where these are stated.

Notes: * + - Requirements shall be written in a clear, direct and precise manner and that they shall result in accurate and uniform interpretation, so that parties making use of the CAS normative document are able to derive from the contents of the normative document have a common understanding of its meaning and intent.
		- Requirements shall be written in terms of results or outcomes, together with limiting values and tolerances, where pertinent.
		- Requirements shall be stated unambiguously using wording that is objective, valid and specific.
 |  |  |
| 1. Are all measurement values expressed in SI units (International System of Units)?
 |  |  |
| 1. Does the CAS cover the following typical elements of a conformity assessment scheme?
	* **selection** of the object(s) of conformity assessment, including selecting specified requirements to be assessed and planning information collection and sampling activities;
	* **determination**, including the use of one or more determination methods (e.g. test, audit and/or examination) to develop complete information regarding fulfilment of the specified requirements by the object of conformity assessment or its sample;
	* **review and attestation**, including the review of evidence from the determination stage, and a subsequent attestation that the object of conformity assessment has been reliably demonstrated to fulfil the specified requirements, and any subsequent marking or licensing and their related controls, where applicable;
	* **surveillance** (where applicable), including the frequency and extent of surveillance activities and reassessments to ensure the object of conformity assessment continues to fulfil the specified requirements.
 |  |  |
| 1. If the CAS involves sampling, which procedures are required for sampling? (To gain consistent and reproducible results, sampling methods should be based, whenever possible, on statistical methods provided in International Standards.)
 |  |  |
| 1. Are there test methods or inspection procedures involved in the CAS? Where are these described?
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| 1. Does the CAS consider the use of marks of conformity? If yes, the SO shall provide evidence to demonstrate how it has protected those marks and laid down rules for their use in accordance with the requirements of the conformity assessment standard chosen.
 |  |  |
| 1. Provide evidence that the CAS was designed by persons demonstrably competent in that capacity. The competence shall cover both the technical field of expertise and the conformity assessment procedure used.

Note: CABs may be involved in the development process of CASs within the limitations given in the standards used for their accreditation. |  |  |
| 1. Provide evidence that the interested parties for the CAS were analysed, identified and consulted, and that any issue has been solved”.
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| 1. Provide evidence that the CAS is validated, considering the details given in clause 3.1.6. As a minimum validation must demonstrate that the CAS has successfully completed a test period, demonstrating that it is ‘fit for purpose’ (i.e. capable of consistently achieving its stated objectives). As a minimum the validation should demonstrate that:
	* + the conformity assessment, as described, is practicable?
		+ the determination activities as described quantify or in other ways identify and confirm the characteristics which the SO intends and expects to identify and which constitute the basis for conformity assessment?
		+ the requirements are specified in a way that ensures reproducibility and reliability of results?
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| **Ordningsejers egen bedømmelse, del 2,** (jf EA 1/22 A-AB: 2023, Annex 1) | **Ordningsejers svar****Vælg og udfyld én af de 4 muligheder** | **DANAKs bedømmelse** |
| **Calibration and testing (including medical tests)*** The application area (object, matrix, scope); Calibration and test methods;
* Performance characteristics of methods;
* Requirements applicable to laboratories, supplementary to international standards for laboratories, for example ISO/IEC 17025 or ISO 15189;
* Requirements against which the object is to be tested. These requirements may be international standards, or legal requirements, or standards set out within the sector or specifications of a group of manufacturers;
* Specific requirements concerning e.g. internal and/or external quality control procedures and/or performance characteristics, if any.
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| **Inspection*** The application area (object, matrix, scope);
* Type of Inspection Body (A, B, C)
* Requirements against which the object of inspection is to be judged. These requirements may be international standards, or legal requirements, or standards set out within the sector or specifications of a group of manufacturers;
* Inspection methods, if relevant, including any examinations which need to be performed as part of the conformity assessment activity;
* Requirements applicable to inspection bodies, supplementary to ISO/IEC 17020.
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| **Certification*** The object of certification: Type of management systems; or Products, services and processes; or Persons (expertise, competence);
* Requirements against which the object of certification shall be assessed and certified. These requirements may be laid down in international standards, or standards or specifications set out within the sector or specifications of a group of manufacturers;
* Description of the certification system;
* Requirements applicable to certification bodies, supplementary to the international standards for certification bodies.
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| **Verification/Validation*** The object of validation/verification (claim)
* The sector
* Requirements against which the declaration is to be validated or verified. These requirements may be international standards, or legal requirements, or standards set out within the sector or specifications of a group of manufacturers;
* Validation/verification program
* Requirements applicable to validation/verification bodies, supplementary to ISO/IEC 17029.
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