1. Master data on scheme owner, scheme and auditor

| **EA 1/22** | **No.** | **Information about the scheme owner** |  |
| --- | --- | --- | --- |
| **Section 3.1.1** |  | Name/company: |  |
| **Section 3.1.1** |  | Type of legal entity: |  |
|  |  | Court/ reg. no. / at: |  |
|  |  | Address: |  |
|  |  | Web address: |  |
|  |  | Contact: |  |
|  |  | Authorised representative:[[1]](#footnote-1) |  |
|  |  | Number of members: (where relevant) |  |
|  |  | Membership rules / association statutes / articles of association of: |  |
|  |  | I acknowledge and agree that all information concerning this application may be passed on to the competent supervisory authority pursuant to Section 2 of the German Regulation on the Entrustment of the Accreditation Body (AkkStelleGBV). | Yes |

| **EA 1/22** | **No.** | **General information on the submitted conformity assessment scheme[[2]](#footnote-2)** | |
| --- | --- | --- | --- |
|  |  | **Scheme number:** |  |
|  |  | **Name/acronym where applicable:** |  |
|  |  | Applicant is scheme owner | Yes |
| Applicant is conformity assessment body (CAB) or intends to seek accreditation in the event of a positive scheme evaluation. | Yes |
|  |  | DAkkS department: |  |
|  |  | Technical unit: |  |
|  |  | **Allocation of regulated area:** (if relevant) |  |

1. Brief description of the conformity assessment scheme

| **EA 1/22** | **No.** | **Requirement** | **Explanation** | | **Reference to annex[[3]](#footnote-3)** |
| --- | --- | --- | --- | --- | --- |
| **Annex 1, no. 5;**  **Section 3.2.1** |  | **Conformity assessment type**  Which conformity assessment process is to be applied under the scheme and indication of the Level 3 standards. A rationale for the **choice** is required. |  | |  |
| **Annex 1, no. 19** |  | **Planned proof of conformity**  (inspection report, certificate, quality seal)  A sample must be included. |  | |  |
| **Annex 1, no. 6** |  | **National basis for evaluation**  ISO/IEC 17011, 17000 Annex A  DAkkS-71 SD 0 016 – Rule for review of the determination of eligibility of new private conformity assessment schemes for accreditation.  Relevant parts of the “ISO-CASCO toolbox”.  **Any other requirements?** | No  Yes / description: | |  |
|  |  | **EU basis for evaluation**  (EA 1/22 (2014) – EA Policy, Criteria and Procedure for the Evaluation of Conformity Assessment Schemes under the EA MLA).  **Any other requirements?** | No  Yes / description: | |  |
| **Section 3.2.4** |  | Are there any legal requirements concerning conformity assessment activities?  If YES, please explain. | No  Yes / description: | |  |
| **Section 3.1.2** |  | The scheme owner (SO) has the authority to establish and change the requirements of the conformity assessment scheme. | No  Yes | |  |
| **Section 3.1.3** |  | The SO is capable of cooperation with the “Home AB” (competent national accreditation body). | No  Yes | |  |
| **Section 3.1.5** |  | The SO commits to accepting results from CABs accredited by any EA MLA signatory (for the relevant scope) that meet the requirements laid down by the SO. | No  Yes | |  |
| **Section 3.1.8** |  | The SO must keep all active national accreditation bodies (NABs) and CABs informed of relevant information and developments relating to the conformity assessment scheme, in particular planned changes to requirements. | No  Yes | |  |
| **Annex 1, no. 2** |  | Is the conformity assessment scheme currently used by CABs accredited by an EA member? | No  Yes / explanation: | |  |
| **Annex 1, no. 7** |  | Has the SO established NAB scheme-specific requirements? | No | |  |
| Yes, described in the scheme product: |  |

1. Brief presentation of the scheme owner

| **EA 1/22** | **No.** | **Requirement** | **Explanation** | **Reference to annex3** |
| --- | --- | --- | --- | --- |
|  |  | Brief company history. |  |  |
|  |  | Presentation of any other relevant activities performed by the applicant outside the activity as CAB or SO. |  |  |
|  |  | Relations to or links with other organisations (in particular manufacturers, service providers, buyers) and authorities, both at European and national level (if any) |  |  |
|  |  | Technical areas of activity (e.g. aviation, food safety) |  |  |
| **Section 3.1.4; Annex 1, no. 4** |  | Provision of evidence demonstrating market support and need for the new scheme.5 |  |  |
| **Section 3.2.2** |  | Has the scheme owner defined scheme-specific requirements for the operation of CABs wishing to use the scheme? If yes, please describe these specific requirements and include the relevant requirement documents. In addition, an outline of how these requirements are made publicly available is required. |  |  |
| **Annex 1, no. 8** |  | Does the scheme owner (by itself or through another organisation) perform any kind of assessment (or equivalent) of the CAB? If yes, please describe and include the requirement documents. |  |  |
|  |  | Does the scheme owner request DAkkS to accept or take into account assessments in accordance with section 3.7 during the accreditation process? If yes, please describe and include the relevant documents. |  |  |
|  |  | Does DAkkS or EA request cooperation with the scheme owner on issues other than the accreditation of CABs? If yes, please specify the scope and/or extent of cooperation, and include the documents where this is described. |  |  |

1. General information on the scheme

| **EA 1/22 / MD 25** | **No.** | **Requirement** | **Explanation** | **Reference to annex3** |
| --- | --- | --- | --- | --- |
| **Annex 1, no. 18** |  | Does the scheme consider the use of marks of conformity? If so, the scheme owner must provide evidence to demonstrate how these marks are protected and lay down rules for the use of these marks. The scheme owner must monitor compliance with these rules. |  |  |
| **Section 3.1.7** |  | Agreements on use of the scheme by accredited CABs must guarantee at least that the CAB uses the scheme as it is, without any limitations and without any additions. How is this implemented contractually? |  |  |
| **Annex 1, no. 19** |  | Evidence must be provided that the scheme was developed by demonstrably competent persons. The competence must cover both the technical field of expertise and the conformity assessment procedure used.  **Note:** CABs may be involved in the development process of schemes within the limitations given in the standards used for their accreditation. |  |  |
| **Section**  **3.1.4** |  | Evidence must be provided that the interested parties for the scheme have been analysed and identified. Relevant interested parties must be consulted. |  |  |
|  |  | Is there a written assessment and analysis that the criteria of the schemes do not violate the WTO Codex/Article 43 of Directive 2014/24 EU and Regulation (EU) 1025/2012 (requirements for technical ICT specifications)?[[4]](#footnote-4) |  |  |
| **Section 3.2.4** |  | Conformity assessment schemes in the voluntary sector with requirements applicable to objects of conformity assessment must neither contradict, nor simply be the fulfilment of, applicable legal requirements. |  |  |
| **Section 3.1.6** |  | The applicant must demonstrate that the requirements for a conformity assessment scheme are met by submitting a **validation report**. The validation report must contain the minimum information set out in Annex 1 and a copy must be provided. | |  |
|  |  | If there are innovative and complex schemes requiring a procedure after the pilot phase, the timeline and the responsibilities of DAkkS must be described. |  |  |

Other aspects of scheme evaluation

| **EA 1/22** | **No.** |  |  |
| --- | --- | --- | --- |
| **Section 3.2.3** |  | Do the scheme-specific requirements contradict the requirements of ISO/IEC 17011, EU Regulation (EC) 765/2008 or EA, MLA or ILAC and IAF mandatory documents? | No  Yes, description: |

Annex 1 Explanation of the validation report

The applicant must validate the scheme and as a minimum must demonstrate that the scheme has successfully complete a test period and is therefore ‘fit for purpose’ (i.e. capable of consistently achieving its stated objectives). The validation must include the following:

* A description of the purpose of the scheme;
* A description of the requirements of the scheme;
* An analysis of the appropriateness of the established requirements for fulfilling the defined purpose of the scheme;
* A description of the methods to be used for determining fulfilment of the requirements;
* As mentioned in clause 6.2 ISO/IEC 17065, the identification of the applicable requirements of the relevant international standards;
* 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;
* Evidence that the described conformity assessment is practicable;
* Evidence that the determination activities as described quantify or in other ways identify and confirm the characteristics which the scheme owner intends and expects to identify and which constitute the basis for conformity assessment;
* Evidence that the requirements are specified in a way that ensures reproducibility and reliability of results.

1. Legal representation is not permitted in the technical inspection, as applicants must demonstrate their personal competence. [↑](#footnote-ref-1)
2. Completed by the office of Deutsche Akkreditierungsstelle GmbH (DAkkS). [↑](#footnote-ref-2)
3. The applicant/scheme owner provides the relevant cross references and information. [↑](#footnote-ref-3)
4. Not applicable to CAB applicants [↑](#footnote-ref-4)