Note: Decision 03/2018 was deleted

Decision No	Decision Text	Confirmation AKB
DAkkS 1/2016 **14.09.2016**	**"Further applicable documents" and "in conjunction with" in annexes to certificates of DAkkS** In newly issued annexes to certificates of DAkkS, there are no **"further applicable documents"** and documents **"in conjunction with"** (however referred to) listed on principle. This rule may be disregarded only if sectoral rules, sectoral decrees or definitions by power conferring authorities expressly provide for it.	**Regulation / Decision confirmed by AKB 31.08.2016**
DAkkS 2/2016 **14.09.2016**	**Testing/calibration/examination with equipment/devices not owned by the laboratory** **"External equipment/devices"** A Conformity Assessment Body (CAB) must be equipped with the required equipment/devices, measuring and testing instruments (hereinafter referred to as "testing instruments") for such testing, calibration or examination procedures for which it intends to obtain or holds accreditation. I.e. it must be able to have the testing instruments required for them available. Testing instruments are deemed available if they are owned by the CAB or are leased, rented or borrowed by it or available to it in any other way. This requires evidence of a proper and appropriate written contractual basis about the use/availability of the testing instruments by the CAB. The contractual framework terms and conditions must be appropriate and suitable for the required use, such as e.g. period of use, length of use, frequency of use, managerial authority, confidentiality, data protection/trade secret protection (e.g. of electronic measuring/raw data), etc., for technically accurate performance of the test/calibration/examination and for the period of accreditation. The same shall apply for testing instruments used/available outside of the CAB's own fixed equipment, i.e. also for those installed at the site of another legal entity, owned/held by them and used by the laboratory on a contractual basis in line with the above requirements, if applicable. In cases in which a CAB has to or may perform analytic or metrological testing/calibrations/examinations, e.g. at the manufacturer's site with the manufacturer's testing instruments, the contract must also provide for the CAB having sole power of disposal over such testing instruments and managerial authority over personnel performing such tests/calibration/examination, if applicable.	**Regulation / Decision confirmed by AKB 31.08.2016**

	In all of the aforementioned cases, CAB must be able to provide proof of suitability, serviceability and functional control, maintenance, calibration of testing instruments or qualification of additional operating personnel (ancillary personnel). Such responsibility and provision of proof may not be delegated in any case, not even by contract. None of the aforementioned availability options releases the CAB from the responsibility to independently perform the tests/calibrations/examinations with contractually bound personnel and to determine and document all management and technical requirements of DIN EN ISO/IEC 17025 or DIN EN ISO 15189 for these tests/calibrations/examinations and to provide proof of their being complied with.	
DAkkS 03/2016 **14.09.2016**	**Reissue of test reports in the case of change of trade name/brand name of tested products** Test reports may be changed only in case of correction of test results or to add data/information missing at the time of testing. The unique identification of the test sample must be provided. Such identification may be supplemented by trademarks/names provided by the manufacturer and may be designated as such. The approach in which laboratories reissue test reports within the scope of validity of their accreditation if the trade name/brand name of the previously tested products was changed is not allowed without testing such product again. It is also not allowed if the reissued test report refers to the original test report. The test laboratory may not assume the responsibility of confirming that the product with the new trade name/brand name is absolutely identical to the previously tested product; such responsibility falls to the laboratory's customer. *This decision was passed within the scope of the 33th General Assembly of "European Co-operation for Accreditation (EA)" and must be implemented by all accreditation bodies which are members of the EA.* *The decision takes effect as of the date of publication by DAkkS.*	**Regulation / Decision confirmed by AKB 31.08.2016**
DAkkS 01/2018 **19.03.2018**	**Impartiality of notified bodies** With the accreditation of bodies which strive a notification as a notified body the accreditation of DAkkS ensures the sufficient impartiality if these bodies for processing conformity assessment activities. For the use of article R17 (4) of the decision 768/2008/EG or the relevant regulations within the respective directive or provision it is necessary that concerned bodies do not offer	**Determination of regulation / decision applied 12.07.2018**

	any consultancy (e. g. technical support or consultancy for passing the product testings). This concerns the consultancy of producers for all types of products which are listed within the accreditation certificate or its annex. This applies to these products and for all of those producers, depending on whether they are customers of conformity assessment activities of its products of the notified body or not. In that respect DAkkS does not apply to the document CERTIF 2015-02 Rev03. This determination also applies to bodies which strive an accreditation as certification- or inspection body of type A within the non-regulated area. This resolution was adopted during the 40th General Assembly of the "European Co-operation for Accreditation" (EA) and all accreditation bodies which are member of EA must implement this. The decision becomes applicable on the date of publication by DAkkS.	
DAkkS 02/2018 **19.03.2018**	**Inadmissibility of disclaimers in addition of an certification agreement according to note 4.1.2 ISO/IEC 17065** 1. It is inadmissible to leave visible risks of a product unconsidered within the certification decision as a conformity assessment body and to amend a disclaimer within a conformity assessment confirmation and/or certification agreement, in which certain functions or risks of the product will be excluded which might influence fundamental safety requirements. 2. An accredited conformity assessment body shall not be restricted to process conformity assessment confirmations even if the producer deviates from requirements of the relevant standard or due to lack of standards or which are under revision or the product has additional risks because of the addition of new, innovative functions and interfaces (especially digitization) by the producer. On the contrary, the accredited conformity assessment body specifies in the certification agreement with the producer which additional effort may arise die to deviations from standards or die to new product characteristics and risks in order to	**Determination of regulation / decision applied 12.07.2018**

	prove compliance with the basic safety objectives on the basis of the current state of the art. Concerned accreditation activities: ISO/IEC 17065 The interpretation decision will be part of the next revision of the DAkkS-regulation 71 SD 0 001. Reason: The agreement of disclaimers may damage the confidence to accredited conformity assessment evidences permanently as the conformity assessment statement would become completely non-transparent. The ISO/IEC 17065, note 4.1.2, does not permit disclaimers or restrictions within the certification agreement. The ultimate responsibility for the safety of products and services rests with the producer, provider or distributor. To process a conformity assessment and issuing a conformity assessment evidence must not repeal the responsibility. The use of recognized standards by the producer or distributor is voluntary. It is the sole responsibility of the producer which technical specifications will be set for the product in full self-responsibility. For the application of harmonized standards, only the conformity assumption for the compliance of the fundamental safety requirements is relevant for the market access. When standards from recognized standards organizations are used, it is generally assumed that the state of the art is observed, which could have advantages in terms of criminal and product law. Although the producer may deviate from the standard or the product may be produced according to specifications, if applicable, which are marked within the standard procedure as “draft”, if these better reflect the state of the art as the valid standard. Furthermore, the producer may deviate from the standard to implement new innovative solutions. Exceptions are only conformity assessment testings against so called “technical regulations” (according to RL 1535/2015) of a public authority which are to be applied “dejure” or “defacto” due to legal or regulatory regulations. In any case the producer must declare the product or service, because of its ultimate responsibility, with the fundamental safety requirements and must provide all necessary	

	documents and specifications to the conformity assessment body to enable an independent third party assessment. Then, it is the task of the accredited conformity assessment body to examine the compliance of fundamental safety requirements normally based on the conformity determination of the product characteristics with the requirements of recognized standards. If nonconformities to the recognized standards are discovered, the producer must present, for the conviction of the conformity assessment body, that its determined specifications have an **equivalent safety level** in every respect. Otherwise standards would not be voluntary any more. Therefore, the conformity assessment body must evaluate each nonconformity of the standard regarding technical equivalence. If the equivalence cannot be confirmed a positive conformity assessment evidence must not be issued. Additional expenses for the equivalence evidence must be contractually bounded by the accredited conformity assessment body within the certification agreement according to note 4.1.2 ISO/IEC 17065.	