



BELAC ACTIVITIES : DESCRIPTION AND CRITERIA FOR SELECTION

The only valid versions of the documents of the BELAC management system are those available from the internet website (www.belac.fgov.be).

English translation for information only
French and Dutch version remain the authoritative documents

Date of implementation : 25.09.2023

HISTORY OF THE DOCUMENT

Revision and date of approval	Reason for the revision	Scope of the revision
0 CC 27.01.2011	New document	
1 CC 26.10.2012 and consultation by correspondence 17.12.2012	<p>Principles with respect to the accreditation of testing and medical laboratories for activities that are systematically subcontracted.</p> <ul style="list-style-type: none"> - Extension of BELAC scope for the accreditation of validation and verification bodies according to ISO 14065: Adding reference to the series of BELAC documents 2-405 in case of specific accreditation requirements for a specific conformity assessment activity. - Explicit mention of GHG validation and verification bodies as a new type of conformity assessment bodies. 	<p>New points 4.2.2 and 4.3.2</p> <p>Point 3.2</p> <p>New point 4.11</p>
2 Secr. 10.06.2014	<p>Update of reference to accreditation standards</p> <p>Suppression of the possibility of accreditation according to ISO/IEC 17025 for activities that can be covered by EN ISO 15189</p>	<p>Point 4</p> <p>Point 4.2.1</p>
3 CC 03.05.2016	Update of reference to accreditation standards	Point 4
4 CC 27.10.2016	<p>Subcontracting by laboratories: specific provisions</p> <p>Conformity assessment activities within the framework of product certification</p>	<p>Points 4.2.2 and 4.2.3</p> <p>Point 4.2.1, 4.6 and 4.9</p>
5 CC 19.04.2017	<p>Update of reference to accreditation standards</p> <p>Definition of laboratories activities, systematic sub-contracting, according to ISO/IEC 17025:2017</p> <p>Provisions for the reduction of the scope of BELAC activities</p>	<p>Point 4</p> <p>Points 4.2</p> <p>Point 3.2</p>
6 Secr 25.06.2019	Update of reference to accreditation standards	Point 4
7 CC 29.06.2020	<p>Accreditation of sampling activities by calibration laboratories</p> <p>Accreditation of sampling activities by testing laboratories</p> <p>Accreditation of sampling activities by inspection bodies</p>	<p>Point 4.1.1</p> <p>Point 4.2.1</p> <p>Point 4.6</p>

	Note: conformity statement and opinion/interpretation	Point 4.1.1
8 Secr 10.02.2021	Editorial changes	
9 CC 01.12.2022	The document has been completely revised. The main changes concern outsourcing, sampling, declarations of conformity, opinions/interpretations and the performance of critical calibrations	Entire document
10 Secr. 25.09.2023	Update of reference to standards (transition EN ISO 15189:2012 to EN ISO 15189:2022, transition EN ISO/IEC 17043:2010 to EN ISO/IEC 17043:2023 and transition ISO/TS 22003 :2013 to ISO 22003-1 :2022)	Point 4

BELAC ACTIVITIES:

DESCRIPTION AND SELECTION CRITERIA

1. AIM OF THE DOCUMENT AND REFERENCES TO STANDARDS

This document aims to provide a general description of the scope of activities of BELAC and of the criteria to be complied with for the selection of an activity under the BELAC scope. The specific provisions for the implementation of the accreditation process in the different accreditation programs are detailed under the relevant documents of the BELAC series 2 and 3

This document refers to and complies with the relevant sections of the EC Regulation 765/2008, the standard NBN EN ISO/IEC 17011 and the relevant EA / IAF / ILAC guidelines and complementary requirements.

A list (document BELAC 6-017) identifies, for each type of conformity assessment activity, the main technical fields in which BELAC is currently active. The list complements the present document and is regularly updated; it has a strictly informative character and does not presume of the ability of BELAC to extend its activities to other domains.

2. RECIPIENTS

The members of the Co-ordination Commission
The members of the Accreditation Board
The BELAC secretariat
The assessors
The accredited bodies

3. GENERAL PROVISIONS

3.1. The scope of BELAC and its limits

As the sole national accreditation body, BELAC is entitled

- to grant accreditations under Regulation (EC) 765/2008 according to requirements that are fixed in harmonized standards and, where applicable, additional requirements, such as those included in the relevant sector schemes to carry out specific conformity assessment activities for the types of conformity assessment bodies listed under point 4;
- to cover all potential sectors of conformity assessment and all technical sectors, in both the regulated and non-regulated sectors.

3.2. Extension of the scope

The extension of the BELAC scope of activities to a new accreditation field (i.e. an accreditation standard not yet recognised by BELAC) will only be decided subject to

- a positive advice of the National Council of Accreditation; the interest expressed by the concerned sector, the expectations of the stakeholders, the position of the regulatory authorities when relevant and the situation at the international level will be considered;
- endorsement by the Minister of Economy.

In case of extension of the scope of activities of BELAC to significantly new types of conformity assessment activities (including related new conformity assessment schemes) within an already active accreditation field, the endorsement by the Co-ordination Commission is solely required.

In both cases, a documented review of feasibility is performed by the BELAC secretariat; the specific aspects described under point 4 are taken into consideration.

In case of extension of the BELAC scope, the implementation includes all or part of the following elements, depending on the specific situation:

- the identification of access to the relevant expertise and training, when relevant, of assessors and experts with the necessary technical competence;
- the development of specific guidance documents in order to allow for a harmonized implementation of the accreditation requirements and for a standardised lay-out of the accreditation documents (accreditation certificates and scopes);
- modifications to relevant documents of the management system
- consulting and informing the concerned parties.

In case the feasibility review leads to the identification of specific accreditation requirements (either applicable to the conformity assessment body or to BELAC itself), these requirements are documented and made publicly available under the form of a document of the BELAC 2-405 series (BELAC 2-405 – NAME ACTIVITY). These documents can not contradict or exclude requirements from the relevant international standards.

In case BELAC considers reducing the scope of its activities, a process similar to the one set in place for an extension is used, limited to the relevant elements. The following complementary elements are included:

- deleting all relevant documentation in the management system
- checking whether the legal aspects are complied with;

- fixing the rules for the termination of the valid accreditations and other transition provisions.

4. SPECIFIC PROVISIONS FOR EACH TYPE OF CONFORMITY ASSESSMENT BODY

4.1. Calibration laboratories (EN ISO/IEC 17025:2017)

4.1.1 As far as calibration laboratories are concerned, accreditation may cover:

- all types of laboratories;
- the physical quantities and types of instruments, provided traceability may be achieved;
- the chemical and biological quantities provided traceability may be achieved;
- calibration activities performed according to standardised or published methods or European or national regulations or according to methods developed in-house by the laboratory ;
- declarations of conformity (*) and/or opinions or interpretations (**) associated with the calibrations for which an accreditation has been granted.

Note:

(*) A conformity statement is the expression of the level of correspondence between a calibration result and a specification, norm or documented requirement. This means that the assignment of a class or category to the calibrated product, based on comparison of the calibration result with the limits that define the different classes, can also be considered as a declaration of conformity.

(**) An opinion or interpretation is the result of a process aiming to explain the meaning or the applicability of a calibration result. An opinion or interpretation is formulated by a technically qualified person with the necessary competence and ability to express a professional judgment and is based on evidences.

The laboratory can choose to issue declarations of conformity and/or opinions/interpretations (associated with the calibrations for which an accreditation has been issued) outside of accreditation. This must be contractually agreed with the customer in advance and it must be transparent and clear in the reporting that these declarations of conformity and/or opinions/interpretations fall outside of accreditation. This is not possible when declarations of conformity and/or opinions/interpretations are inherently included in the calibration method as stated in the accreditation scope

- the performance of reference measurements in laboratory medicine, provided that the requirements of EN ISO/IEC 17025 are complemented with those of EN ISO 15195:2019.

4.1.2 Calibration laboratories will in principle not obtain accreditation for activities that they do not or cannot perform themselves. For that reason, systematic outsourcing of a complete calibration activity, as included in the accreditation scope, is not allowed. Systematic outsourcing of an activity means that this activity is permanently outsourced and is therefore never carried out by the laboratory itself. A calibration laboratory may, in case of force majeure (eg excessive workload, defective device, etc.) temporarily outsource a full calibration activity, as included in the accreditation scope. Temporary outsourcing of an activity due to force majeure (whereby the activity cannot be performed by the laboratory itself in that period of time) shall in principle not exceed 3 months. In case the laboratory has not been able to solve the causes of force majeure after 3 months, the BELAC secretariat will be informed. In doing so, the laboratory will submit a risk analysis and action plan, as well as an estimate of the time

span that is deemed necessary to eliminate the causes of force majeure. The Accreditation Board will decide on the further procedure. If the temporary outsourcing is expected to last longer than 6 months, a voluntary suspension should be considered.

Systematic outsourcing of a step or part of the practical performance of a full calibration activity (as included in the accreditation scope):

- is permitted if it is provided for in national or European regulations or has been previously approved by the relevant regulatory authority;
- may be authorized by the Accreditation Bureau to accommodate, on a case-by-case basis, specific situations specific to an accredited laboratory or specific to a sector of activity. The following conditions must be in that case be met:
 - the reasons for which a laboratory relies on systematic outsourcing of part of a calibration must be documented. In addition, the risks associated with this outsourcing must be identified;
 - the parts of the calibration that are part of the systematic outsourcing may only represent a limited percentage of the total of the accredited calibration;
 - the outsourced activities must be entrusted to a laboratory that is also accredited for the calibration concerned;
 - the accredited laboratory must be capable of demonstrating its technical competence with regard to the activities that are outsourced. In addition, the accredited laboratory must carry out its own checks on these outsourced activities;
 - the outsourcing laboratory remains ultimately responsible for the complete calibration. This from the moment of sampling or receipt of the item up to and including the release of the final report;
 - the applicant for the calibration must be informed in advance about the conditions/conditions under which the calibration will be performed.

The part of the calibration activity that is systematically outsourced is explicitly mentioned in the accreditation scope.

4.1.3 The accreditation of only part of a calibration activity is not allowed.

4.2. Testing laboratories (EN ISO/IEC 17025:2017)

4.2.1 As far as testing laboratories are concerned, accreditation may cover:

- all types of laboratories;
- all types of products, materials or equipment in all technical sectors, with the exception of the activities of medical laboratories that can be covered by EN ISO 15189;
- tests carried out according to standardized or published methods, according to European or national regulations or according to methods developed in-house by the laboratory itself;;
- sampling carried out according to standardized or published methods or European or national regulations or according to methods developed in-house by the laboratory, provided that the sampling is followed by the performance of one or more tests
 - o by the testing laboratory itself
 - or
 - o by another accredited testing laboratory. In that case, the sampling methods must be determined and recorded in consultation with the laboratory performing these tests;

Sampling cannot be limited to merely drawing up a sampling plan, but should also include the actual sampling activities.

- declarations of conformity (*) and/or opinions or interpretations (**) associated with the tests for which an accreditation has been granted

Note:

(*) A declaration of conformity is the expression of the level of compliance of a test result with a specification, standard or requirement. This means that the assignment of a class or category to the tested product, based on comparison of the test result with the limits that define the different classes, can also be considered as a declaration of conformity.

(**) An opinion or interpretation is the result of a process in which the meaning or applicability of a result obtained from a test is explained. An opinion or interpretation is formulated by a technically qualified person on the basis of his knowledge and professional judgment and must be supported by evidence.

The laboratory can choose to issue declarations of conformity and/or opinions/interpretations (associated with the tests for which an accreditation has been issued) outside of accreditation. This must be contractually agreed with the customer in advance and it must be transparent and clear in the reporting that these declarations of conformity and/or opinions/interpretations fall outside of accreditation. This is not possible when declarations of conformity and/or opinions/interpretations are inherently included in the test method as stated in the accreditation scope

4.2.2 In principle, testing laboratories will not obtain accreditation for activities that they do not (or cannot) perform themselves. For that reason, systematic outsourcing of a full test activity, as included in the accreditation scope, is not allowed. Systematic outsourcing of an activity means that this activity is permanently outsourced and is therefore never carried out by the laboratory itself. A testing laboratory may, in case of force majeure (e.g. excessive workload, defective device, etc.) temporarily outsource a full calibration activity, as included in the accreditation scope. Temporary outsourcing of an activity due to force majeure (whereby the activity cannot be performed by the laboratory itself in that period of time) shall in principle not exceed 3 months. In case the laboratory has not been able to solve the causes of force majeure after 3 months, the BELAC secretariat will be informed. In doing so, the laboratory will submit a risk analysis and action plan, as well as an estimate of the time span that is deemed necessary to eliminate the causes of force majeure. The Accreditation Board will decide on the further procedure. If the temporary outsourcing is expected to last longer than 6 months, a voluntary suspension should be considered.

Systematic outsourcing of a step or part of the practical performance of a complete testing activity (as included in the accreditation scope):

- is accepted in case it is explicitly allowed by a (inter)national or European regulation or has been previously agreed by the concerned regulatory authority;
- may be accepted by the Accreditation Board to accommodate, on a case by case basis, situations specific to an accredited laboratory or specific to a sector of activity. The following conditions need to be complied with:
 - the laboratory shall provide motivation for systematic subcontracting of the part of a testing process and the associated risks will be identified;
 - the parts of the testing process that are systematically subcontracted will represent only a limited part of the accredited testing;
 - the activities shall be subcontracted to a laboratory accredited for the concerned tests;

- the accredited laboratory shall be able to demonstrate its technical competence with respect to the subcontracted activities and shall keep due control on them;
- the accredited laboratory remains solely responsible for the whole testing process, starting with the acceptance of the test object up to issuing the final test report;
- the accredited laboratory shall inform its customer in advance about the conditions of performance of the test.

The part of the testing activity that is systematically outsourced is explicitly mentioned in the accreditation scope

4.2.3 The accreditation of part of a testing process (e.g. preparation of a sample prior to testing) is not allowed.

4.2.4 When a testing laboratory carries out critical calibrations itself in the context of its testing activities, the evaluation will be carried out by BELAC on the basis of the relevant EN ISO/IEC 17025 requirements with regard to calibration (see also BELAC 2-003). However, as a standard procedure, no EN ISO/IEC 17025 certificate with associated accreditation scope is issued for these calibration activities, since these activities are fully part of the process of the testing activities and therefore implicitly form part of the EN ISO/IEC 17025 accreditation as a testing laboratory.

4.3. Medical laboratories (EN ISO 15189:2012 (until 05.12.2025) or EN ISO 15189: 2022)

4.3.1 As far as medical laboratories are concerned, accreditation may cover:

- all types of laboratories ;
- all types of samples, sectors and techniques provided they fall under the scope of the EN ISO 15189:2012 standard;
- the activities of Point of Care Testing, provided that the requirements of EN ISO 15189:2012 (until 05.12.2025) are complemented with those of EN ISO 22870:2016. In case of accreditation according to ISO 15189:2022, the requirements regarding POCT are included in ISO 15189:2022 and ISO 22870 is no longer applicable.

4.3.2 The provisions documented under 4.2.2, 4.2.3 and 4.2.4 are also applicable to the medical laboratories.

4.4. Proficiency Testing Organisers (EN ISO/IEC 17043:2010 (until 31.05.2026) or EN ISO/IEC 17043:2023)

As far as the organisation of proficiency testing is concerned, accreditation may cover:

- all potential technical sectors;
- targeted campaigns or campaigns with a repetitive character ;

For the supporting calibration and/or testing activities, which fully fit into the process of the organization of proficiency testing (e.g. in the context of characterization or determination of homogeneity and/or stability of the PT item), the proficiency test organizer must ensure that competence for these activities is guaranteed. The evaluation of this will therefore be part of the BELAC audit.

When supporting calibration and/or testing activities are carried out by the proficiency testing organizer himself, these are evaluated by BELAC on the basis of the relevant requirements of EN ISO/IEC 17025 (and/or EN ISO 15189 if relevant).

However, no EN ISO/IEC 17025 and/or EN ISO 15189 certificate with associated accreditation scope is issued for this as a standard procedure, as these activities are fully part of the process of organizing proficiency tests and are therefore implicitly part of EN ISO/IEC 17043 accreditation.

An organizer of proficiency tests can, however, at any time submit an accreditation request for these calibration and/or testing activities if he wishes to receive a separate accreditation certificate with the corresponding scope: in that case an evaluation will be carried out by BELAC that covers all requirements of EN ISO/IEC 17025 (and/or EN ISO 15189 if relevant).

Where these supporting calibration and/or testing activities are outsourced, it is the responsibility of the proficiency testing organizer to demonstrate that the relevant subcontractor(s) is (are) competent for the activities entrusted to him (them). and for this complies (comply) with the relevant requirements of EN ISO/IEC 17025 (and/or EN ISO 15189 if relevant). The evaluation of this will also be part of the BELAC assessment, taking into account the requirements for subcontractors.

4.5. Reference Materials Producers (EN ISO 17034:2016)

As far as the production of reference materials is concerned, accreditation may cover:

- all potential technical sectors ;
- punctual productions or productions with a repetitive character;

For the supporting calibration and/or testing activities, which fully fit into the process of making reference materials (e.g. in the context of characterization or determination of homogeneity and/or stability of the reference material), the producer of reference materials must ensure that competence for these activities is guaranteed. The evaluation of this will therefore be part of the BELAC assessment.

When supporting calibration and/or testing activities are carried out by the producer of reference materials himself, these are evaluated by BELAC on the basis of the relevant requirements of EN ISO/IEC 17025 (and/or EN ISO 15189 if relevant).

However, no EN ISO/IEC 17025 and/or EN ISO 15189 certificate with associated accreditation scope is issued for this as a standard procedure, as these activities fully fit into the process of making reference materials and are therefore implicitly part of EN ISO 17034. accreditation.

A producer of reference materials can nevertheless at any time submit an accreditation request for these calibration and/or testing activities if he wishes to receive a separate accreditation certificate with the corresponding scope: in that case an evaluation will be carried out by BELAC that covers all the requirements of EN ISO /IEC 17025 (and/or EN ISO 15189 if relevant).

When these supporting calibration and/or testing activities are outsourced, it is the responsibility of the reference materials producer to demonstrate that the relevant subcontractor(s) is (are) competent for the activities entrusted to him (them). and for this complies (comply) with the relevant requirements of EN ISO/IEC 17025 (and/or EN ISO 15189 if relevant). The evaluation of this will also be part of the BELAC assessment, taking into account the requirements for subcontractors.

4.6. Inspection bodies (EN ISO/IEC 17020:2012)

As far as inspection bodies are concerned, accreditation may cover:

- all types of inspection bodies;

- inspections of a product, service, process, installation or of their design and the determination of their conformity with normative or regulatory (European or (inter)national) provisions, or with national or international conformity assessment schemes either regulated or developed by private operators (see also under point 5);
- sampling carried out according to standardized or published methods or regulatory European or (inter)national provisions or according to methods developed internally by the inspection body, provided that the sampling is followed by the execution of:
 - o inspections carried out by the inspection body itself;
 or
 - o inspections performed by another accredited inspection body. The sampling methods are determined in consultation with the inspection body that carries out the inspections. These provisions must be specified in the contract with the applicant for the sampling;
 or
 - o testing by an accredited testing laboratory and the sampling methods have been determined in consultation with the laboratory performing the test(s). These provisions must be specified in the contract with the applicant for the sampling

In all these cases, sampling should take into account the relevant requirements of EN ISO/IEC 17025:2017 applicable to sampling activities.

When an inspection body itself carries out critical calibrations in the context of its inspection activities, the evaluation will be carried out by BELAC on the basis of the relevant EN ISO/IEC 17025 requirements with regard to calibration (see also BELAC 2-003). As a standard procedure, however, no EN ISO/IEC 17025 certificate with associated accreditation scope is issued for these calibration activities, as these activities are fully part of the process of the inspection activities and therefore implicitly form part of the EN ISO/IEC 17020 accreditation as an inspection body.

4.7. Certification bodies for management systems (EN ISO/IEC 17021-1:2015)

As far as the certification of management is concerned, accreditation may cover:

- certification according to international standards for management systems, provided that the requirements of EN ISO/IEC 17021-1 are complemented with the requirements of:
 - ISO/IEC 17021-2:2016 for the certification bodies providing audit and certification of environmental management systems;
 - ISO/IEC 17021-3:2017 for the certification bodies providing audit and certification of quality management systems;
 - ISO/IEC TS 17021-10:2018 for certification bodies providing audit and certification of occupational health and safety management systems;
 - ISO TS 22003:2013 (until 31.12.2024) or ISO 22003-1:2022 for the certification bodies providing audit and certification of food safety management systems;
 - ISO/IEC 27006:2015+ Amd1:2020 for the certification bodies providing audit and certification of information security management systems (ISMS);
 - ISO 50003:2021 for the certification bodies providing audit and certification of energy management systems.
- certification according to national or international conformity assessment schemes,

regulated or in the private field (see also under point 5);

4.8. Environmental verifiers (EN ISO/IEC 17021-1:2015 and EMAS Regulation EC n° 1221/2009)

As far as environmental verification is concerned, accreditation may cover:

- a conformity assessment body as defined by Regulation 765/2008 but not a physical or moral person;
- all relevant sectors of activity as defined by the nomenclature of economic activities set up by the EC Regulation 1893/2006.

4.9. Certification bodies for products, processes and services (EN ISO/IEC 17065:2012)

As far as the certification of products, processes and services is concerned, accreditation may cover:

- certification of any type of product , process or service;
- certification according to national or international standards, normative documents or certification schemes, regulated or in the private field (see also under point 5);
- certification of trust services for electronic identification and electronic transactions under the Regulation (EU) No 910/2014 on condition of fulfilling the requirements of the ETSI EN 319 403 in addition to the EN ISO/IEC 17065 requirements.

The conformity assessment activities (testing or inspection) performed by the product certification body itself are part of the product certification process and are covered by the accreditation according to EN ISO/IEC 17065. Therefore, as a standard procedure, no certificate with corresponding scope for EN ISO/IEC 17020, EN ISO/IEC 17025 and/or EN ISO/IEC 17021-1 is issued for these activities.

A certification body for products can nevertheless at any time submit an accreditation request for these inspection and/or testing activities if it wishes to receive a separate accreditation certificate with the corresponding scope: in that case an assessment will be carried out by BELAC that covers all the requirements of EN ISO/IEC 17020, EN ISO/IEC 17025 and/or EN ISO/IEC 17021-1.

4.10. .Certification bodies for personnel (EN ISO/IEC 17024:2012)

As far as the certification of persons is concerned, accreditation may cover each type of certification scheme for persons provided it complies with the requirements of the standard EN ISO/IEC 17024 and in particular annex A.

4.11 Greenhouse gas validation and verification bodies (EN ISO 14065:2013 until 31 December 2023 or EN ISO/IEC 17029:2019 + EN ISO 14065:2021)

As far as the activities of greenhouse gas validation and verification bodies are concerned, accreditation may cover all activities performed within the framework of a national or European legislation.

5. POLICY FOR CONFORMITY ASSESSMENT SCHEMES

5.1. Definitions

5.1.1. Conformity assessment scheme

With conformity assessment scheme is meant a set of documents that fix:

- 1) the requirements or reference documents to be used by the conformity assessment bodies (e.g.: test methods, regulatory requirements according to which inspection or certification needs to be performed...);
- 2) the requirements placed on conformity assessment bodies that fix provisions for their organisation, working, staff, equipment, content of reports;
- 3) the requirements placed on accreditation bodies that assess the conformity assessment bodies.

5.1.2. Owner of a conformity assessment scheme

Body that establishes a conformity assessment scheme

5.2. International conformity assessment schemes

Conformity assessment activities performed within the framework of an international conformity assessment scheme may be covered by accreditation provided the following conditions are complied with:

- the conformity assessment scheme has been formally endorsed by EA, ILAC or IAF;
- EA, ILAC or IAF have not taken a negative position with respect to the scheme.

In all other cases, accreditation will only be possible based on the following conditions:

- The scheme owner will be invited to contact EA with the view to get formal endorsement of the scheme;
- The scheme will:
 - o be formally documented and publicly available;
 - o be developed, approved and maintained under the responsibility of a formally identified public or private scheme owner;
 - o demonstrate a clear market support, which may also include governmental initiatives or regulatory needs;
 - o rely on a conformity assessment process that fall into the scope of internationally agreed accreditation requirements;
 - o not include scheme specific requirements placed on conformity assessment bodies that contradict or exclude any of the accreditation requirements;
 - o not include scheme specific requirements placed on BELAC that contradict or exclude any of the requirements of the standard EN ISO/IEC 17011, the EC Regulation 765/2008 and the relevant EA, ILAC and IAF provisions.
- BELAC commits itself to respect the EA, ILAC or IAF decisions with respect to the scheme as soon as the scheme gets formally endorsed or refused by these organisations.

5.3. National conformity assessment schemes

Accreditation is possible provided that the conformity assessment scheme complies with the requirements for the international conformity assessment schemes and brings added value with respect to existing federal, regional or community regulatory requirements.
