

EU notified body Conformity Assessment process

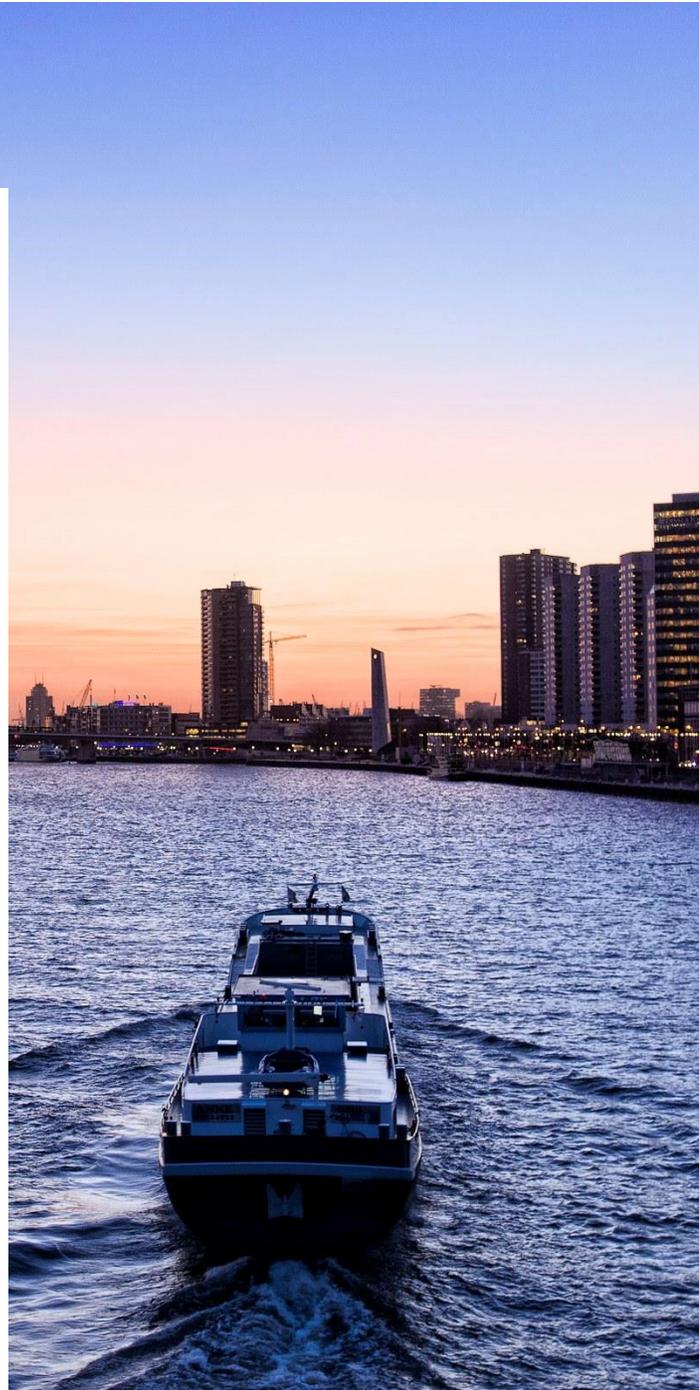
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1. Definitions

1.1

The in this document mentioned terms are defined in the RD.004 (EMCI Register list of terms and conditions).

1.2

Where this document is used for Conformity Assessment under the EMCI Register NANDO scope, the term 'Conformity Assessment scheme' shall mean to also include the applicable rules stemming from the NANDO scope related to the Conformity Assessment that is being performed. 'Certification' and/or 'Inspection' scheme shall also be meant when 'Conformity Assessment scheme' is said.

1.3

Where the work being performed under this document is done against ISO 17065:2012 Conformity Assessment shall mean to include certification.

1.4

Where the work being performed under this document is done against ISO 17020:2012 Conformity Assessment shall mean to include inspection.

2. Purpose

2.1

This document regulates how EMCI Register assesses conformity of products as far as it relates to its Notified Body status (NANDO 2832) or other scopes that follow from work performed under ISO/IEC 17065 or ISO 17020.

2.2

EMCI Register shall confine its requirements, evaluation, review, decision, and surveillance (if any) to those matters specifically related to the scope of Conformity Assessment.

2.3

The EMCI Register will use this Conformity Assessment process for the Conformity Assessment of:

- Products requiring Conformity Assessment as specified in the EMCI Register NANDO scope 2832.
- Products requiring Conformity Assessment under the “Regeling lozen buiten inrichtingen”.
- Other products such to the discretion of EMCI Register.

3. Conformity Assessment process

3.1

Each Conformity Assessment issued by EMCI Register must have followed one or multiple Conformity Assessment processes. Conformity Assessment, as defined in Article 2.3, must be carried out against ISO 17065:2012 or ISO 17020:2021, in case of unclarity the applicable ISO 17000 standard prevails.

3.2

A Conformity Assessment process is the culmination of the individual (sub) processes laid out in this document. A Conformity Assessment process can consist of the following:

- Application
- Application review
- Conformity Assessment advice
- Conformity Assessment plan
- Conformity Assessment file
- Evaluation
- Conformity Assessment decision
- Certificate
- Complaint

The above-mentioned terms are explained in this document.

3.3

If the Conformity Assessment process is successful, it must contain all (except complaints) the above (sub) processes/ documents.

3.4

A Conformity Assessment process results in:

- If applicable, a product being certified against a norm for which EMCI Register is appointed to certify against.
- If applicable, a product receiving an inspection report against a norm for which EMCI Register is appointed to provide inspections against.
- The extension/modification of an existing Conformity Assessment
- The transferring of a Conformity Assessment from a different notified body to EMCI Register.

3.5

If the client has requested the extension, modification, or upgrade/downgrade of an existing Conformity Assessment, EMCI Register starts a new Conformity Assessment process. It will determine during the application review phase the applicable norm elements and required work.

3.6

EMCI Register may also invite external observers with or without consultation of the client. These observers will be given the right to view all documents relating the Conformity Assessment process. The EMCI Register supervising bodies and the appointing government(s) are always external observers.

3.7

EMCI Register office operations is not authorized to meddle with the content-based/norm-specific matters of the Conformity Assessment process. If the person described in 9.1 is also part of office operations for a product, they may only signal problems for which the assigned lead auditor must make a decision. In case of deadlock, the HCD prevails.

3.8

A product must meet the Conformity Assessment requirements and those set by any related norms, directives, and other set requirements.

3.9

At the end of the Conformity Assessment process, no matter the outcome/result, EMCI Register asks for feedback from each at the time of completion of the Conformity Assessment activities. It will do so using SurveyMonkey, Wufoo (in accordance with RD.002 (Quality manual)), or face-to-face. The quality officer has permanent access to all filled-in forms and must respond to negative reviews.

3.10

EMCI Register shall inform it's notifying authority of the following:

- Any refusal, restriction, suspension or withdrawal of certificates
- Any circumstances affecting the scope of and conditions for notification
- Any request for information on conformity assessment activities performed which they have received from market surveillance authorities
- On request, conformity assessment activities performed within the scope of their notification and, any other activity performed, including, cross-border activities and subcontracting

3.11

EMCI Register shall provide the other bodies notified under the same community harmonization legislation (or other forms of legislation) carrying out similar conformity assessment activities and covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

3.12

EMCI Register will store all Conformity Assessment documents in accordance with PD.007.

3.13

Internal approval for documents can be achieved through email or phone-based communications. Legally binding approval (i.e. of the contract by the client) must always be done through SOP.003.

3.14

In the event of any unclarity or interpretation issue arising from the Conformity Assessment process, EMCI Register retains the right to seek advice from an advisory mechanism of its choosing and to integrate this advice into the resolution of the above. Should EMCI Register wish to invoke this right, the Conformity Assessment process will be on hold until the matter is decided. EMCI Register will involve relevant human resources, including the lead auditor, in this decision. The decision EMCI Register takes to resolve the above will be binding.

4. Application

4.1

Each product that EMCI Register certifies must have a valid application

4.2

An application must contain at least:

- The product information
- The client information including company registration and contact details
- Information required to determine what norm is required for Conformity Assessment

4.3

For CE Conformity Assessment the list of documents that a client must have in their possession for Conformity Assessment is specified in the legal act against which Conformity Assessment will be provided. This is the legal act as also referred to in the EMCI Register NANDO scope. The client agrees to these requirements through the signing of the contract.

5. Application review

5.1

Each application received by EMCI Register is subject to a review process.

5.2

EMCI Register is free to deny any application. However,

- Access to the Conformity Assessment process shall not be conditional upon the size of the client or membership of any association or group, nor shall Conformity Assessment be conditional upon the number of Conformity Assessments already issued. There shall not be undue financial or other conditions.
- EMCI Register Conformity Assessment should be open to all clients and products if they fall within the scope of Conformity Assessment that EMCI Register operates.
- EMCI Register is free to refuse a client or product if there has been evidence of non-compliance with EMCI Register rules, national or international legislation or (suspected) participation in criminal activities.

5.3

EMCI Register will communicate the denial to the client. The client is allowed then to alter the application and start the Conformity Assessment process in accordance with Article 4 to be processed accordingly or file a complaint.

5.4

Each review must yield a Conformity Assessment advice as internal verification of the viability of the project in accordance with ISO 17065:2012 article 7.3 or ISO 17020:2012 article 7.

5.5

EMCI Register must determine at the application review process whether it is able to carry out the Conformity Assessment process requested by the client. This includes but is not limited to ensuring required testing equipment is available and the intellectual, experience and audit capacity/capability exists (by assigning qualified persons) within EMCI Register to certify against the desired norm and whether sufficient technical information is present or obtainable. If EMCI Register cannot executed a Conformity Assessment activity it shall document this and be reported to the quality officer.

5.6

EMCI Register and the lead auditor must be able to select the applicable norm(s) for this product from the norm cache. EMCI Register may only proceed with the Conformity Assessment if the Conformity Assessment requirements are contained in specified standards and/or other normative documents as stored in the normative cache. If the norm is not found it must either be added, or the Conformity Assessment request cannot go ahead. If applicable the appropriate authority, government, committee or accrediting body will be consulted.

5.7

The lead auditor and office operations must sign off on the Conformity Assessment advice to ensure that EMCI Register has the competence and abilities to carry out the desired Conformity Assessment activities.

6. Conformity Assessment advice

6.1

In accordance with Article 5.3 a review of an application for Conformity Assessment will always yield a Conformity Assessment advice. A Conformity Assessment advice is an internal document designed for verify EMCI Register is able to start and carry out the Conformity Assessment.

6.2

A Conformity Assessment advice must contain:

- Whether EMCI Register is capable of performing the actions requested in the application
- What norm the product in the application will be certified against
- What audit team will be responsible for the Conformity Assessment

6.3

Once a Conformity Assessment advice is issued EMCI Register will set up a draft Conformity Assessment agreement in accordance with TD.001.

6.4

A Conformity Assessment advice must appoint a lead auditor who will be responsible for evaluating the product. Office operations may only appoint a lead auditor whom has been appointed with the appropriate competency code in accordance with RD.005 (QUALIFICATION PROFILES) for this evaluation.

6.5

The Conformity Assessment advice must be accepted and approved by the lead auditor.

6.6

A Conformity Assessment advice must contain a Conformity Assessment plan as described in article 7.

6.7

At the client's request the lead auditor will give explanation on how the Conformity Assessment process will proceed and what evaluations will be carried out as well as answering any other questions the client may have.

7. Conformity Assessment plan

7.1

Each Conformity Assessment advice will contain a Conformity Assessment plan.

7.2

A Conformity Assessment plan will contain the expected dates for Conformity Assessment and the essential procedures required for Conformity Assessment. It must contain:

- Expected start and end date of Conformity Assessment
- Expected submittal date to HCD

7.3

The Conformity Assessment plan is open to modification if additional evaluation activities are required which were not evident at the start of the Conformity Assessment process.

8. Conformity Assessment file

8.1

EMCI Register is responsible, through the legally enforceable commitment made in TD.001 (Conformity Assessment agreement), for the management of all information obtained or created during the performance of Conformity Assessment activities and the execution of PD.001 (Conformity Assessment process).

8.2

Every certified, currently being certified, or certified in the past product must have a corresponding Conformity Assessment file. The Conformity Assessment file will contain all information, documents, evidence, correspondence etc. related to the Conformity Assessment of the product.

8.3

The Conformity Assessment file will contain at least:

8.3.1 Always:

- Identification of the client.
- An application for Conformity Assessment & identification of the product
- The product technical information.

8.3.2. If Conformity Assessment advice was accepted:

- The Conformity Assessment agreement signed by EMCI Register and the client
- The Conformity Assessment plan

8.3.3. If Conformity Assessment was successful:

- As mentioned under 8.3.2 and additionally:
 - The standard(s) and other normative document(s) to which conformity has been established and if applicable certified
 - The evaluation audit report(s)
 - The Conformity Assessment decision
 - The certificate and/or inspection report if applicable

8.3.4

The Conformity Assessment file must contain records to demonstrate that all Conformity Assessment process requirements are fulfilled. The documents as mentioned in 8.3.3 must demonstrate that all process requirements have been effectively fulfilled. Any relevant communication with the client may also be included.

8.4

The Conformity Assessment file is stored according to PD.007 (Document management).

8.5

Documents may be stored in different locations if relevant to the process of Conformity Assessment and they must be retrievable by unique project number

9. Conformity Assessment decision

9.1

After finalizing of all required evaluations without non-conformities a Conformity Assessment decision must be created.

9.1.1

Before the Conformity Assessment decision is created, EMCI Register may ask a second qualified lead auditor to perform a remote inspection of the Conformity Assessment file.

9.1.2

If applicable, after approval from the supervising lead auditor the Conformity Assessment decision will be set up in accordance with article 9.2.

9.2

The Conformity Assessment decision is issued by the head of Conformity Assessment upon receiving the recommendation of a Conformity Assessment file by the lead auditor and performing a review of that file. The Conformity Assessment decision must be based on TD.003.

9.3

The Conformity Assessment decision can lead to:

- Acceptance:
 - This can only be done if the Conformity Assessment file is completed, including the presence of a technical file meeting all requirements.
- Denial:
 - In which case the product is denied. The client must then resubmit an application.
- Improvement required:
 - The client/lead auditor will be given an X amount of days, at the discretion of the head of Conformity Assessment, to comply. Failure to do this will lead to automatic denial.

9.4

In case of acceptance, the board of EMCI Register retains the right to deny the Conformity Assessment on non-content-based grounds. If it does not exercise this, the product will be certified.

9.5

EMCI Register must inform the client of all Conformity Assessment decisions regardless of status and provide explanation hereto.

9.6

In case of acceptance, formal Conformity Assessment documentation shall only be issued after, or concurrent with, the following:

- The decision to grant or extend the scope of Conformity Assessment has been made (to be documented in a Conformity Assessment decision).
- Conformity Assessment requirements have been fulfilled (to be documented in evaluation report(s))
- The Conformity Assessment agreement has been completed/signed (to be placed in the Conformity Assessment file)

9.7

The EMCI Register board must sign all issued certificates through SOP.003.

10. Certificate & Conformity Assessment documentation

10.1

A by the board of EMCI Register approved Conformity Assessment decision will always lead to the issuing of a certificate.

10.2

The certificate will be issued for the specific standard/norm/directive/law determined during the review phase and for the specific product submitted during the application phase.

10.3

Usage of the certificate and all issued marks, are subject to PD.004 (Rules for the use of marks and certificates).

10.4

Every certificate issued by EMCI Register can be revoked and suspended as described in PD.001 (Conformity Assessment process).

10.5

EMCI Register will keep a public register of certificates, regardless of status, as described in Article 20.

10.6

Each certificate will have a unique identification number which must be visible in any distribution variant of the certificate. If the product Conformity Assessment norm/directive/standard/law defines a number format EMCI Register will follow this, in all other cases the following format will be followed:

- [type-Conformity Assessment]-[product name]-[issue date]-[expiry-date]-[unique alphanumeric sequence]

Additionally, EMCI Register certificates contain at least the following:

- Name of the product
- Applied norm
- Period of validity
- Date of issuing
- Any comments left by EMCI Register. These will be binding.
- The EMCI Register Conformity Assessment number issued by the notifying authority body (NANDO number).
- The signature of the board

10.7

Certificates are solely signed by the board.

11. Lead Auditor

11.1

EMCI Register will appoint a lead auditor for each Conformity Assessment process.

11.2

The lead auditor must meet the lead auditor competency profile described in RD.005 (Qualification profiles).

11.3

The lead auditor will be responsible for guiding the audit process, ensuring that the product up for Conformity Assessment meets the applicable standards in the norm(s), creating a recommendation for the Conformity Assessment decision and performing evaluations to support their claims.

11.4

The lead auditor must only be tasked with evaluating the product against the standards in the norm and may only recommend the Conformity Assessment file to the head of Conformity Assessment if the product conforms to the standards in the norm(s).

11.5

The lead auditor is responsible for submitting the Conformity Assessment file for review to the head of Conformity Assessment. The lead auditor is not involved in the decision of granting the Conformity Assessment of the product.

11.6

The lead auditor shall have an agreement and sign PD.006 (Code of conduct).

11.7

The lead auditor must determine the evaluation results without burden and consultation of EMCI Register, unless a request hereto is made by the lead auditor. The lead auditor is independently authorized to determine the advice for the Conformity Assessment decision. In case of unclarity in the requirements for Conformity Assessment article 3.14 applies.

11.8

The human resources involved in conformity assessment activities shall not be remunerated in a way that influences the results of the conformity assessment activities.

12. Head of Conformity Assessment

12.1

The head of Conformity Assessment is responsible for providing the Conformity Assessment decision and the review (the head also specifically fulfills the role as described in ISO 17065:2012 article 7.5 when this standard applies) of the Conformity Assessment file in the Conformity Assessment process.

12.2

The task of the head of Conformity Assessment is to ensure:

- The correct protocol was followed when certifying a product.
- The management system performed effectively and if not, report to the quality officer and the board.
- Identifying (potential) nonconformities and if detected, report to the quality officer and the board
- Identifying (potential) impartiality issues and if detected, report to the quality officer, board and impartiality committee

Hereto the head of Conformity Assessment has the obligation to sign off for the above-mentioned points on all Conformity Assessments performed by EMCI Register.

12.3

The head of Conformity Assessment must meet the head of Conformity Assessment competency profile as described in RD.005 (Qualification profiles).

12.4

The head of Conformity Assessment shall have an agreement with EMCI Register and must sign PD.006 (Code of conduct).

12.5

The head of Conformity Assessment must make the Conformity Assessment decision without burden and consultation of EMCI Register, unless a request hereto is made by the head of Conformity Assessment.

12.6

The head of Conformity Assessment is independently authorized to create the Conformity Assessment decision.

13. Evaluation and audits

13.1

As part of the Conformity Assessment process, EMCI Register may have to conduct one or multiple evaluations of the product against the relevant norm/standards/directive/law determined in the review process.

13.2

All evaluations must be carried out by the lead auditor assigned to the corresponding Conformity Assessment process.

13.3

All evaluations must be planned and accepted by both EMCI Register and the client.

13.4

All evaluations will be concluded with an audit report. This audit report will be placed in the Conformity Assessment file.

13.5

The lead auditor is responsible for creating the audit report. The audit report will be shared with the client.

13.6

The audit report will contain:

- Results of all evaluation activities both that were found during the evaluation and audit
- Clarification of non-conformities

13.7

If one or more nonconformities have arisen, and if the client expresses interest in continuing the Conformity Assessment process, the Conformity Assessment body shall provide information regarding the additional evaluation tasks needed to verify that nonconformities have been corrected.

13.8

If the client agrees to completion of the additional evaluation tasks that require site visits, the process specified in article 13 shall be repeated to complete the additional evaluation tasks. The additional evaluation shall be documented in the Conformity Assessment file.

13.9

If EMCI Register omits activities through the reliance on Conformity Assessments

- it has already granted to the client,
- that the client already possesses,
- or has already been granted to other clients,

it will reference these Conformity Assessments in the technical file. If requested by the client, EMCI Register shall provide justification for the omission of activities.

13.10

EMCI Register shall only rely on evaluation results related to Conformity Assessment completed prior to the application for Conformity Assessment, where it takes responsibility for the results and satisfies itself that the body that performed the evaluation fulfils the requirements contained in PD.001 (Conformity Assessment process, article 17) and those specified by the Conformity Assessment scheme.

13.11

EMCI Register shall carry out the evaluation activities that it undertakes with its internal resources and shall manage outsourced resources in accordance with the Conformity Assessment plan. The products shall be evaluated against the requirements covered by the scope of Conformity Assessment and other requirements specified in the Conformity Assessment scheme.

13.12

At the discretion of the lead auditor, if not all required technical files/documentation is present the evaluation will be postponed or cancelled.

14. Norm cache

14.1

EMCI Register will retain a cache of normative documents for as far as they relate to the (potential) Conformity Assessment activities that EMCI Register will carry out. These can be documents such as CE Module descriptions, relevant ISO norms etc.

14.2

The norm cache and its contents are stored according to the PD.007 (Document management).

14.3

The norm cache is a non-public document folder that may only be accessed by employees and EMCI Register appointed organizations.

14.4

Changes to the normative cache must be logged according to PD.007 (Document management) or by a relevant authority.

15. Normative changes

15.1

In the lifespan of EMCI Register, norms that EMCI Register has, will, or may certify / inspect against can change.

15.2

EMCI Register will check once every six months whether changes have occurred to documents in the norm cache or whether the contents of the norm cache require addition/deletion. The quality officer will carry out these changes.

15.3

While checking for required change the quality officer must also check for announced changes and act accordingly.

15.4

Normative changes may lead to changes in the Conformity of products. PD.001 (Conformity Assessment process) and the scheme must be consulted to see how changes in Conformity Assessment norms that lead to non-conformity should be addressed.

15.5

15.5.1

When the Conformity Assessment scheme introduces new or revised requirements that affect the client, EMCI Register shall ensure these changes are communicated to all clients via email.

15.5.2

The client is requested to show proof of the implementation of the changes.

15.5.3

A EMCI Register appointed lead auditor shall verify the implementation of the changes by its clients and shall take actions required by the scheme.

15.6

EMCI Register shall consider other changes affecting Conformity Assessment, including changes initiated by the client, and shall decide upon the appropriate action.

15.7

The actions to implement changes affecting Conformity Assessment shall include, if required, the following:

- Evaluation
- Review
- Decision
- Issuance of revised formal Conformity Assessment documentation to extend or reduce the scope of Conformity Assessment
- Issuance of Conformity Assessment documentation of revised surveillance activities (if surveillance is part of the Conformity Assessment scheme)

And shall be done according to PD.001 (Conformity Assessment process)

16. No use of harmonized standards

16.1

A client may request to have non-harmonized standards used in their audit if allowed by the certification scheme.

16.2

EMCI Register will appoint a lead auditor to review these standards and advise EMCI Register on whether this standard is allowed. Additional information may be asked of the client.

16.3

EMCI Register will add these standards to the normative cache if they are applicable and where required.

16.4

The use of non-harmonized standards may be combined with additional costs for the review and application.

16.5

EMCI Register may choose to formally accept certain standards without review or based on past reviews, if so it must document this in a board decision or SOP.

17. Resource management

17.1. Evaluation activities via internal resources or other resources under our direct control

17.1.1.

When EMCI Register performs evaluation activities, either:

- with its internal resources, or
- with other resources under our direct control,

EMCI Register shall ensure to meet the applicable requirements stemming from

- EMCI Register's NANDO scope, and
- the relevant International Standards:
 - For product Conformity Assessment:
 - It shall meet the applicable requirements of ISO/IEC 17065
 - In addition: if the product is to be certified under an EU legal instrument as listed in the EMCI Register NANDO scope, it must meet the applicable requirements of this directive
 - For product Conformity Assessment evaluations:
 - The resource must always be ISO/IEC 17065 accredited, or part of an ISO/IEC 17065 accredited organization, or appointed against the applicable standard by an EEA member state.
 - In addition: if the product Conformity Assessment evaluation is performed under an EU legal instrument as listed in the EMCI Register NANDO scope, the resource must also be appointed hereto.
 - For testing or product Conformity Assessment where testing is performed:
 - it shall meet the applicable requirements of ISO/IEC 17025
 - if evaluated by another resource under our direct control, it must be under ISO/IEC 17025 accreditation in accordance with the scope of the required work assignment or test.
 - For inspection or product Conformity Assessment where inspection is performed:
 - it shall meet the applicable requirements of ISO/IEC 17020
 - For management system auditing:
 - it shall meet the applicable requirements of ISO/IEC 17021

17.1.2.

EMCI Register excludes:

- inspection auditing
- management system auditing

17.1.3.

EMCI Register reserves the right to request permission from the Notifying Authority for deviations on the before mentioned principles.

17.1.4.

Any deviation from these requirements must be documented in a board decision.

17.1.5.

The impartiality requirements of evaluation personnel must always meet ISO/IEC 17065:2012 requirements.

17.2 Outsourcing of evaluation activities

17.2.1

When EMCI Register outsources evaluation activities, it shall only be to bodies that meet the applicable requirements of the requirements stemming from

- EMCI Register's NANDO scope, and
- the relevant International Standards:
 - For product Conformity Assessment:
 - It shall meet the applicable requirements of ISO/IEC 17065
 - In addition: if the product is to be certified under an EU legal instrument as documented in the EMCI Register NANDO scope, it must meet the applicable requirements of this instrument.
 - For product Conformity Assessment evaluations:
 - The resource must always be ISO/IEC 17065 accredited, or part of an ISO/IEC 17065 accredited organization or appointed against the applicable standard by an EEA member state.
 - In addition: if the product Conformity Assessment evaluation is performed under an EU legal instrument as documented in the EMCI Register NANDO scope the resource must also be appointed hereto.
 - For testing or product Conformity Assessment where testing is performed:
 - it shall meet the applicable requirements of ISO/IEC 17025
 - if evaluated by another resource, it must be under ISO/IEC 17025 accreditation in accordance with the scope of the required work assignment or test.
 - For inspection or product Conformity Assessment where inspection is performed:
 - it shall meet the applicable requirements of ISO/IEC 17020
 - For management system auditing:
 - it shall meet the applicable requirements of ISO/IEC 17021

17.2.2.

EMCI Register excludes:

- inspection auditing
- management system auditing

17.2.3.

EMCI Register reserves the right to request permission from the Notifying Authority for deviations on the before mentioned principles.

17.2.4.

Any deviation from these requirements must be documented in a board decision.

17.2.5.

The impartiality requirements of evaluation personnel must always meet ISO/IEC 17065:2012 requirements.

17.2.6.

If evaluation activities are outsourced to non-independent bodies (e.g. client laboratories), EMCI Register shall ensure that the evaluation activities are managed in a manner which provides confidence in the results, and that records are available to justify the confidence. The lead auditor assures that the evaluation is executed in a verifiable manner and stores the proof in the Conformity Assessment file. When work is performed under the EMCI Register NANDO scope for FPR, this article is overruled by SOP.006.

17.2.7.

Where EMCI Register subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in EU decision 768/2008, article R17, and shall inform our notifying authority accordingly.

17.2.8.

Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

17.2.9

Lead auditors under contract with EMCI Register which have signed the code of conduct and Conformity Assessment agreement are not considered outsourced parties.

17.3

EMCI Register ensures that required testing equipment is available. If non-available internal or external resources are required for Conformity Assessment a determination must be made during the application review stage and a request must be submitted to the board.

17.4

EMCI Register will keep a list of testing equipment (ID.005).

17.5

If testing equipment is required for a Conformity Assessment and this is not in ownership, or already leased by EMCI Register, the costs will be charged to the client.

17.6

EMCI Register may charge an administration fee to the client for the finding and renting of equipment.

17.7

If the client has testing equipment available EMCI Register may use that equipment to avoid costs. EMCI Register ensures this equipment is qualified according to PD.001 (Conformity Assessment process), in order to avoid any breach of impartiality and to ensure the integrity of the Conformity Assessment process.

17.8

Testing equipment may be explicitly used by the lead auditor or a by the lead auditor appointed person.

17.9

EMCI Register ensures testing equipment is correctly calibrated before use.

17.10

Equipment thought not be required by article 17.3 but required at a later stage may be rented if the proper request is made to the board.

18. Monitoring

18.1

18.1.1

Where required by the applicable standard/norm/directive/regulation EMCI Register will continuously monitor the quality of certified products if this is a type certified product.

18.1.2

Once a year the client is hold to deliver a legal binding statement which declares that all products are built in accordance with the applicable norms and requirements, if allowed by the certification scheme.

18.1.3

EMCI Register clients must, without delay, inform EMCI Register of changes to the product and the client's ability to conform to the Conformity Assessment requirements.

18.1.4

If changes are reported EMCI Register will appoint a lead auditor to evaluate the changes and see if they violate the standards set by the applied norms/directives/standards/laws.

18.1.5

If the changes violate the standards set by the applied norms EMCI Register will create a Conformity Assessment advice that contain the required changes.

18.1.6

The client must accept this advice, or the Conformity Assessment will be revoked.

18.2

18.2.1

As part of the monitoring process the client must setup a register of complaints regarding the product in any way. The client must provide EMCI Register with access to this register and the supporting documentation of how each complaint has been dealt with. If this is denied, or this information is not available, EMCI Register is authorized to revoke the Conformity Assessment.

18.2.2

EMCI Register will keep a publicly accessible complaints system of its own in which the product end users can leave complaint, for as far as they relate to the compliance with the norm/standard/law/directive. EMCI Register will process these complaints and appoint a lead auditor to investigate. These complaints are to be handled according to PD.002 (Complaint procedure).

18.2.3

If a complaint is filed, the client must inform EMCI Register within 10 working days or the client is in violation TD.001 (Conformity Assessment agreement)

18.3

EMCI Register may, at any time and if for good reason, perform a (partial) re-Conformity Assessment and corresponding evaluation. If the client does not consent to this, EMCI Register has the right to suspend the Conformity Assessment.

18.4

EMCI Register will periodically monitor the usage of certificates, marks and company public material.

18.5

In the event of a change, to a certified product or its production, that violates the norm, any applicable regulation, applied standard or Conformity Assessment requirement the corresponding Conformity Assessment is automatically invalid.

19. Non-conformity, Suspension and Revocation

19.1

Every certificate, and corresponding Conformity Assessment can be revoked, suspended or changed by EMCI Register.

19.2

The client is always allowed to request revocation of the certificate for any possible grounds.

19.3

EMCI Register may decide to continue the Conformity Assessment under pre-conditions if a minor non-conformity was determined and this is allowed by the norm. What these conditions are and what is considered a minor non-conformity is up to the individual lead auditor. This continuation must be agreed upon with EMCI Register's appointing body.

19.4

19.4.1

If Conformity Assessment is suspended, EMCI Register shall assign a lead auditor to formulate and communicate the following to the client:

- Actions needed to end suspension and restore Conformity Assessment for the product(s) in accordance with the Conformity Assessment scheme
- A defined timeframe to resolve the issues
- Any other actions required by the Conformity Assessment scheme

19.4.2

These persons shall be competent in their knowledge and understanding of all aspects of the handling of suspended Conformity Assessments.

19.4.3

If successful, the Conformity Assessment will be reactivated.

19.4.4

If the client does not correct the non-conformities within the aforementioned timeframe, EMCI Register will revoke the Conformity Assessment.

19.5

If Conformity Assessment is suspended, EMCI Register shall a lead auditor to formulate and communicate the following to the client:

- Actions needed to end suspension and restore Conformity Assessment for the product(s) in accordance with the Conformity Assessment scheme;
- Any other actions required by the Conformity Assessment scheme.

19.6

If the client wants to reactivate the Conformity Assessment after a suspension (resolve the suspension) a new Conformity Assessment process will be started according to PD.001 (Conformity Assessment process).

19.7

If Conformity Assessment is reinstated after suspension, EMCI Register shall make all necessary modifications to formal Conformity Assessment documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications, exist that the product continues to be certified. If a decision to reduce the scope of Conformity Assessment is made as a condition of reinstatement, EMCI Register shall make all necessary modifications to formal Conformity Assessment documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of Conformity Assessment is clearly communicated to the client and clearly specified in Conformity Assessment documentation and public information.

19.8

Once a Conformity Assessment is revoked it cannot be renewed. To achieve the same/comparable Conformity Assessment status a new Conformity Assessment application must be submitted.

19.9

19.9.1

If Conformity Assessment is terminated (by request of the client), suspended or revoked, EMCI Register shall take actions specified by the Conformity Assessment scheme and shall make all necessary modifications to formal Conformity Assessment documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the product continues to be certified.

19.9.2

If a scope of Conformity Assessment is reduced, the Conformity Assessment body shall take actions specified by the Conformity Assessment scheme and shall make all necessary modifications to formal Conformity Assessment documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of Conformity Assessment is clearly communicated to the client and clearly specified in Conformity Assessment documentation and public information.

19.9.3

Any change in the Conformity Assessment status must be reflected in the public register.

20. Public register

20.1

EMCI Register will maintain a register of certified products and the norm(s) under which they are certified.

20.2

The register is available on request for the verification of certificates.

20.3

The public register will contain:

- The unique certificate numbers
- The product names
- The applied norm(s) and standard(s)
- The status of the Conformity Assessment

20.4

The register must be searchable by the unique certificate number.

21. Complaints

21.1.

It is possible to make complaints against EMCI Register. Complaints will be handled according to PD.002 (Complaints procedure).

22. Standard operating procedures

22.1

EMCI Register maintains several SOP documents. SOP's are procedures EMCI Register uses when certifying a product and for using tools.

22.2

The allowed SOP's for the Conformity Assessment procedure described in this document are:

- SOP.001
- SOP.002
- SOP.003
- SOP.004
- SOP.006
- SOP.007

These are considered as inserted and binding.

22.3

SOP's are used by default and always applicable. If EMCI Register decides not to use an SOP it must describe this in the Conformity Assessment advice in accordance with Article 6. This may only be allowed if that SOP is not required by PD.001

22.4

In the case of 22.3 an alternative procedure must be described and documented.