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Artificial Intelligence — Artificial Intelligence Conformity Assessment

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National foreword

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RAPPORT TECHNIQUE

TECHNISCHER REPORT

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December 2024

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English version

Artificial Intelligence - Artificial Intelligence Conformity Assessment

Intelligence Artificielle - Évaluation de la conformité liée à l'Intelligence Artificielle

Künstliche Intelligenz - Konformitätsbewertung von Künstlicher Intelligenz

This Technical Report was approved by CEN on 25 November 2024. It has been drawn up by the Technical Committee CEN/CLC/JTC 21.

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European foreword

This document (CEN/CLC/TR 17894:2024) has been prepared by Technical Committee CEN/CENELEC JTC 21 “Artificial Intelligence”, the secretariat of which is held by Danish Standards (DS).

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1 Scope

This document sets out a review of the current methods and practices (including tools, assets, and conditions of acceptability) for conformity assessment as relevant for the development and use of AI systems. Among others, it addresses the conformity assessment for products, services, processes, management systems and organizations. It includes an industry horizontal (vertical agnostic) perspective and an industry vertical perspective.

This document focuses only on the process and gap analysis of conformity assessments. It defines the **objects of conformity** related to AI systems and all other aspects of the conformity assessment process. The document also reviews to what extent AI poses specific challenges with respect to assessment of, for example, software engineering, data quality and engineering processes.

This document takes into account requirements and orientations from policy frameworks such as the EU AI strategy and those from CEN and CENELEC member countries.

This document is intended for technologists, standards bodies, regulators and interest groups.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
conformity assessment
demonstration that *specified requirements* (3.2) relating to a product, process, system, person or body are fulfilled

Note 1 to entry: The process of conformity assessment as described in the functional approach in Annex A can have a negative outcome, i.e. demonstrating that the specified requirements are not fulfilled.

Note 2 to entry: Conformity assessment includes activities defined elsewhere in this document, such as but not limited to *testing (6.2)*, *inspection (6.3)*, *validation (6.5)*, *verification (6.6)*, *certification (7.6)*, and *accreditation (7.7)*.

Note 3 to entry: Conformity assessment is explained in Annex A as a series of functions. Activities contributing to any of these functions can be described as conformity assessment activities.

[SOURCE: EN ISO/IEC 17000:2020]

3.2
specified requirement
need or expectation that is stated

Note 1 to entry: Specified requirements can be stated in normative documents such as regulations, standards and technical specifications.

Note 2 to entry: Specified requirements can be detailed or general.

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[SOURCE: EN ISO/IEC 17000:2020]

3.3
accreditation
attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectorial schemes, to carry out a specific conformity assessment activity, according to EU regulation (see [1] and [2])

Note 1 to entry: Accreditation is the last level of public control in the conformity assessment system. It is designed to ensure that conformity assessment bodies (e.g. laboratories, inspection or certification bodies) have the technical capacity to perform their duties. Used in regulated sectors and voluntary areas, accreditation increases trust in conformity assessment. It reinforces the mutual recognition of products, services, systems, and bodies across the EU. [3]

Note 2 to entry: At ISO level accreditation is the formal recognition by an independent body, generally known as an accreditation body, that a certification body operates according to international standards.

[SOURCE: Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0765 (see [1] and [2]) Accreditation of conformity assessment bodies (accessed on 6 November 2023), https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/accreditation-conformity-assessment-bodies_en (see [3])]

3.4
object of conformity assessment
entity to which *specified requirements* (3.2) apply

EXAMPLE Product, process, service, system, installation, project, data, design, material, claim, person, body or organization, or any combination thereof

Note 1 to entry: The term "body" is used in this document to refer to *conformity assessment bodies* (4.6) and *accreditation bodies* (4.7). The term "organization" is used in its general meaning and may include bodies according to the context. The more specific ISO/IEC Guide 2 definition of an organization as a body based on membership is not applicable to the field of *conformity assessment* (3.1).

[SOURCE: EN ISO/IEC 17000:2020]

4 Framework of conformity assessment and objects of conformity assessment

4.1 General

In this clause, an overview of the current conformity assessment schemes for organizations in areas such as cybersecurity is provided, highlighting their pros and cons. It also discusses the necessary adaptations required to make these schemes applicable to AI. Additionally, AI assessment frameworks for organizations are proposed, including relevant AI components. These supports providing a comprehensive understanding of the assessment process of AI systems.

4.2 International accreditation and conformity assessment framework

4.2.1 General

Technical standards are met to achieve accreditation and conformity assessment. However, in the field of conformity assessment and accreditation, different levels are assessed. This is why there is a level

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system, which is outlined in documents EA 1/06 [4] under European Accreditation Multilateral agreement Structure and IAF PR 4 [5] and illustrated in Figure 1.

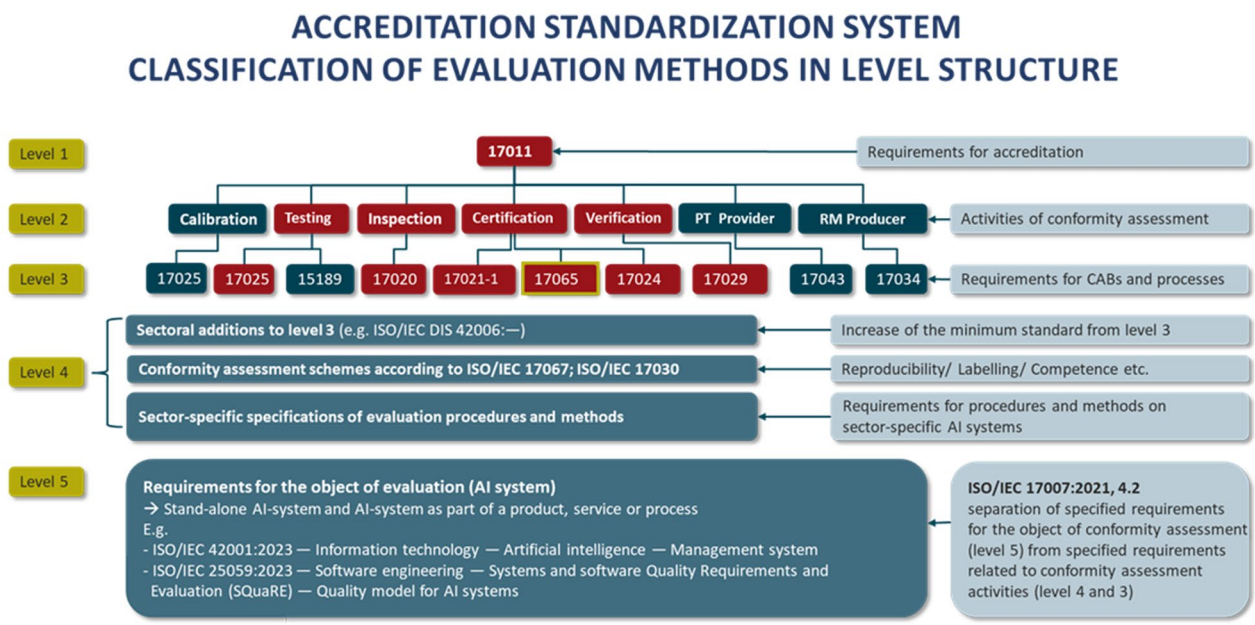

Figure 1 — Accreditation Standardization System - classification of evaluation methods in level structure

The elements which have been identified as needed to be addressed with priority are highlighted in red.

According to EA 1/06 and as depicted in Figure 1, for level 2 the main conformity assessment activities against standards by Conformity Assessment Bodies (CABs), to which accreditation bodies grant accreditation, are highlighted in red. Additional activities include: PT (Proficiency Testing) Providers, Reference Material (RM) Producers as well as calibration activities. At level 3, ISO 17065 [6] (highlighted in green) is identified to be the preferred standard regarding conformity assessment of high-risk AI systems by third parties with respect to the EU AI Act, which was proposed by the European Commission on the 21st April 2021 [7]. From herein reference to the EU AI Act refers to the EU's Artificial Intelligence Act which was unanimously approved by Members of the competent Council of Ministers' Permanent Representatives Committee (Coreper), on the 2nd of February 2024 [8].

For the activity of testing (i.e. "conformity assessment" in the form of testing/inspection/certification, etc. [Level 2 to 4]) there are international standards (ISO/IEC), which define the minimum standard for these organisations and for their (testing) activities. The same applies to the activities of the accreditation authorities, whose tasks and procedures are regulated in the ISO/IEC 17011 standard (see [9]). The reciprocal agreements (MLA/MRA) administered by the international organisations EA, ILAC and IAF are binding under international law. Anyone who falls short of these standards does not test *lege artis* (= in conformity with the law).

4.2.2 Level 5

Starting from level 5, the object of conformity assessment produced or created by an organization is considered. This can include products, processes, services, systems or persons who need to meet specific requirements outlined by laws and regulations, such as the EU AI Act (see [8]) or normative documents such as standards.

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Upon demonstrating conformity with the relevant requirements of a normative document, cited in the OJEU as harmonized standard, the organization benefits from a presumption of conformity with the legally mandated essential requirements set out in the EU AI Act (see [8]). Harmonized standards assist in conferring a presumption of conformity with the requirements set out in laws and regulations.

Accordingly, organisations that demonstrate conformity with the relevant harmonized standards are therefore presumed to be in compliance with the corresponding legally mandated essential requirement set out in the EU AI Act (see [8]).

Examples of level 5 standards:

— EN ISO 9001:2015 (see [10]);

— EN ISO/IEC 27001:2013 (see [11]);

— EN ISO/IEC 27701:2021 (see [12]);

— EN ISO 14064-1:2019 (see [13]);

— EN ISO 13485:2016/A11:2021 (see [14]).

4.2.3 Level 4

When confirming adherence to the relevant criteria pertaining to the subject of the assessment, conformity assessment bodies adhere to explicitly outlined requirements governing the execution of the assessment. In cases where these requirements are particularly defined for certain product categories or specific economic sectors, those are incorporated and met. There can be requirements that further specify the procedure of the necessary conformity assessment activities. These specifying requirements for the conformity assessment procedures are found at level 4 and are fulfilled by the conformity assessment body and not by the distributor or manufacturer of the object of conformity assessment.

In principle, certification schemes and validation and verification programs audited by the accreditation body apply as level 4 for [6] (including activities that may include a test according to [15] or inspection according to [16]) and [17].

Examples of level 4 standards:

— ISO/IEC 42006 [1](see [18]);

— EN ISO/IEC 27006-1:2024 (see [19]);

— ISO/IEC TS 27006-2:2021 (see [20]);

— EN ISO/IEC 17021-3:2018 (see [21]);

— EN ISO 14064-3:2019 (see [22]).

4.2.4 Level 3

A conformity assessment by a first, second, or independent third party is always a defined process of conformity assessment, which contains several steps based on the functional approach defined in EN ISO/IEC 17000:2020, Annex A. The type(s) of conformity assessment activities used differ depending on the object of the conformity assessment. The requirements for these conformity assessment activities are also specified in standards, which are met by the conformity assessment body performing these activities.

[1] Under preparation. Stage at the time of publication: ISO/IEC DIS 42006.

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Examples of level 3 standards (not comprehensive):

— EN ISO/IEC 17021-1:2015 (see [23]);

— EN ISO/IEC 17029:2019 (see [17]);

— EN ISO/IEC 17065:2012 (see [6]).

4.2.5 Level 2

Conformity assessment includes activities such as testing, inspection, as well as certification. To offer these activities, conformity assessment bodies demonstrate their competence. The competence of a conformity assessment body is assessed by means of accreditation, which verifies whether it meets the requirements for the activities it offers. These requirements are located on level 2. Accreditation activities determine the competence of a conformity assessment body, coinciding with level 3 activities.

4.2.6 Level 1

The requirements that the accreditation bodies have to fulfil are referred to as level 1 and are laid down in the standard EN ISO/IEC 17011:2017 (see [9]). Independent of the legal requirements, this harmonized standard in connection with the obligatory documents published by the European and international umbrella organizations of the accreditation bodies form the practical framework for the recognition of accredited conformity assessment activities in the international context.

4.3 Conformity assessment modules

4.3.1 Conformity assessment modules of Decision No 768/2008/EC

The EU AI Act (see [8]) refers to Regulation (EC) 765/2008 (see [1]) and Decision No 768/2008/EC (see [24]). Regulation (EC) 765/2008 [1] sets out the requirements for the accreditation of conformity assessment bodies. At the same time, Decision No 768/2008/EC (see [24]) lays down a 'horizontal menu' of conformity assessment modules and the ways procedures are built of modules (see Table 1).

Table 1 — Conformity Assessment Modules described in Annex II of EU Decision No 768/2008/EC (see [25])

A	**Internal production control**	Covers both design and production. The manufacturer himself ensures the conformity of the products to the legislative requirements (no EU-type examination)
A1	**Internal production control plus supervised product testing**	Covers both design and production. A + tests on specific aspects of each individual product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer.
A2	**Internal production control plus supervised product checks at random intervals**	Covers both design and production. A + product checks at random intervals carried out by a notified body or in-house accredited body based on samples of manufactured products.

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B	**EU-type examination**	Covers design. It is always followed by other modules by which the conformity of the products to the approved EU-type is demonstrated. A notified body examines the technical design and or the specimen of a type and verifies and attests that it meets the requirements of the legislative instrument that apply to it by issuing an EU-type examination certificate. There are 3 ways to carry out EU-type examination: 1) production type, 2) combination of production type and design type and 3) design type
C	**Conformity to EU-type based on internal production control**	Covers production and follows module B. The manufacturer must internally control its production to ensure product conformity against the EU-type approved under module B.
C1	**Conformity to EU-type based on internal production control plus supervised product testing**	Covers production and follows module B. The manufacturer must internally control its production to ensure product conformity against the EU-type approved under module B. C + tests on specific aspects of each individual product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer.
C2	**Conformity to EU-type based on internal production control plus supervised product checks at random intervals**	Covers production and follows module B. The manufacturer must internally control its production to ensure product conformity against the EU-type approved under module B. C + at random intervals a notified body or in-house accredited body tests product on specific aspects based on samples of manufactured products.
D	**Conformity to EU-type based on quality assurance of the production process**	Covers production and follows module B. The manufacturer operates a production (manufacturing part and inspection of final product) quality assurance system to ensure conformity to EU-type. The notified body assesses the quality system.
D1	**Quality assurance of the production process**	Covers both design and production. The manufacturer operates a production (manufacturing part and inspection of the final product) quality assurance system to ensure conformity to legislative requirements (no EU-type, used like D without module B). Notified body assesses the production (manufacturing part and inspection of final product) quality system
E	**Conformity to type based on product quality assurance**	Covers production and follows module B. The manufacturer operates a product quality (=' production' quality without the manufacturing part) assurance system for final product inspection and testing to ensure conformity to EU-type. A notified body assesses the quality system. The idea behind module E is like the one under module D: both are based on a quality system and follow module B. Their difference is that the quality system under module E aims to ensure the quality of the final product, while the quality system under module D (and D1 too) aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E is thus like module D without the provisions relating to the manufacturing process.

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E1	**Quality assurance of final product inspection and testing**	Covers both design and production. The manufacturer operates a product quality (=' production' quality without the manufacturing part) assurance system for final product inspection and testing to ensure conformity to the legislative requirements (no module B (EU-type), used like E without module B). The notified body assesses the quality system. The idea behind module E1 is like the one under module D1: both are based on a quality system. Their difference is that the quality system under module E1 aims to ensure the quality of the final product, while the quality system under module D1 aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E1 is thus like module D1 without the provisions relating to the manufacturing process.
F	**Conformity to EU-type based on product verification**	Covers production and follows module B. The manufacturer ensures compliance of the manufactured products to approved EU-type. The notified body carries out product examinations (testing of every product or random sample checks) to control product conformity to EU-type. Module F is like C2, but the notified body carries out more systematic product checks.
F1	**Conformity based on product verification**	Covers both design and production. The manufacturer ensures compliance of the manufactured products to the legislative requirements. The notified body carries out product examinations (testing of every product or random sample checks) to control product conformity to the legislative requirements (no EU-type, used like F without module B) Module F1 is like A2 but the notified body carries out more detailed product checks.
G	**Conformity based on unit verification**	Covers both design and production. The manufacturer ensures compliance of the manufactured products to the legislative requirements. The notified body verifies every product to ensure conformity to legislative requirements (no EU-type).
H	**Conformity based on full quality assurance**	Covers both design and production. The manufacturer operates a full quality assurance system to ensure conformity to legislative requirements (no EU-type). The notified body assesses the quality system.
H1	**Conformity based on full quality assurance plus design examination**	Covers both design and production. The manufacturer operates a full quality assurance system to ensure conformity to legislative requirements (no EU-type). The notified body assesses the quality system and the product design and issues an EU design examination certificate. Module H1 in comparison to module H provides in addition that the notified body carries out a more detailed examination of the product design. The EU-design examination certificate must not be confused with the EU-type examination certificate of module B that attests the conformity of a specimen 'representative of the production envisaged', so that the conformity of the products can be checked against this specimen. Under EU design examination certificate of module H1, there is no such specimen. The EU design examination certificate attests that the conformity of the design of the product has been checked and certified by a notified body.

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4.3.2 Conformity assessment modules of the EU AI Act

According to Article 43(3) of the EU AI Act (see [8]), "*AI providers for high-risk AI systems, to which legal acts listed in Annex II, section A,* apply *shall follow the relevant conformity assessment as required under those legal acts"*. The following sections provide an overview of the conformity assessment modules (see Table 1) available under that sectorial legislation.

As products under Annex II section A are to follow the conformity assessment under sectorial legislation, it is unclear whether the notified body designated under sectorial legislation requires a specific designation and notification under the EU AI Act (see [8]), or whether the sectorial designation and notification is sufficient, provided the notified body can demonstrate sufficient competence required by the EU AI Act (see [8]) for certain AI technologies, including demonstrating sufficient consideration of the whole range of risks addressed by the EU AI Act (see [8]).

The EU AI Act (see [8]) foresees conformity assessment procedures aligned with modules A and H1 of Decision No 768/2008/EC (see Figure 2 and [24]). However, according to **Article 43(3) of EU AI Act (see [8])**: *"For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, the provider shall follow the relevant conformity assessment as required under those legal acts. The requirements set out in Chapter 2 of this Title shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply."*

Annex VII:

Point 4.3: "*The technical documentation shall be examined by the notified body. Where relevant and limited to what is necessary to fulfil their tasks, the* ***notified body shall be granted full access to the training, validation, and testing datasets*** *used ….*"

Point 4.4: "*In examining the technical documentation, the notified body may require that the provider supplies further evidence or carries out further tests so as to enable a proper assessment of conformity of the AI system with the requirements set out in Title III, Chapter 2. Whenever the notified body is not satisfied with the tests carried out by the provider,* ***the notified body shall directly carry out adequate tests****, as appropriate*."

Point 4.5: **"…** ***after all other reasonable ways to verify conformity have been exhausted and have proven to be insufficient, and upon a reasoned request****, the notified body shall be* ***granted access to the training and trained models of the AI system, including its relevant parameters****. Such access shall be subject to existing Union law on the protection of intellectual property and trade secrets.***"**

Point 4.6: *"Where the AI system is not in conformity with the requirements set out in Title III, Chapter 2, the notified body shall refuse to issue an EU technical documentation assessment certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.*

Where the AI system does not meet the requirement relating to the data used to train it, re-training of the AI system will be needed prior to the application for a new conformity assessment. In this case, the reasoned assessment decision of the notified body refusing to issue the EU technical documentation assessment certificate shall contain specific considerations on the quality data used to train the AI system, notably on the reasons for non-compliance."

Notified body access to source code, training, validation, and testing data sets corresponds to module B (EC type examination), while the notified bodies carrying out tests corresponds to module D (Conformity to type based on quality assurance of the production process) of Decision No 768/2008/EC (see [24]). When only Technical Documentation and Quality Assurance are reviewed, then this corresponds to module H1 (Conformity based on full quality assurance plus design examination)(see Figure 2 and Table 1). Note that rather than module H, module H1 applies as the EU AI Act (see [8]) refers to notified bodies issuing an EU technical documentation assessment certificate (aka EU-design examination certificate following Blue Guide 2022 [25] terminology).

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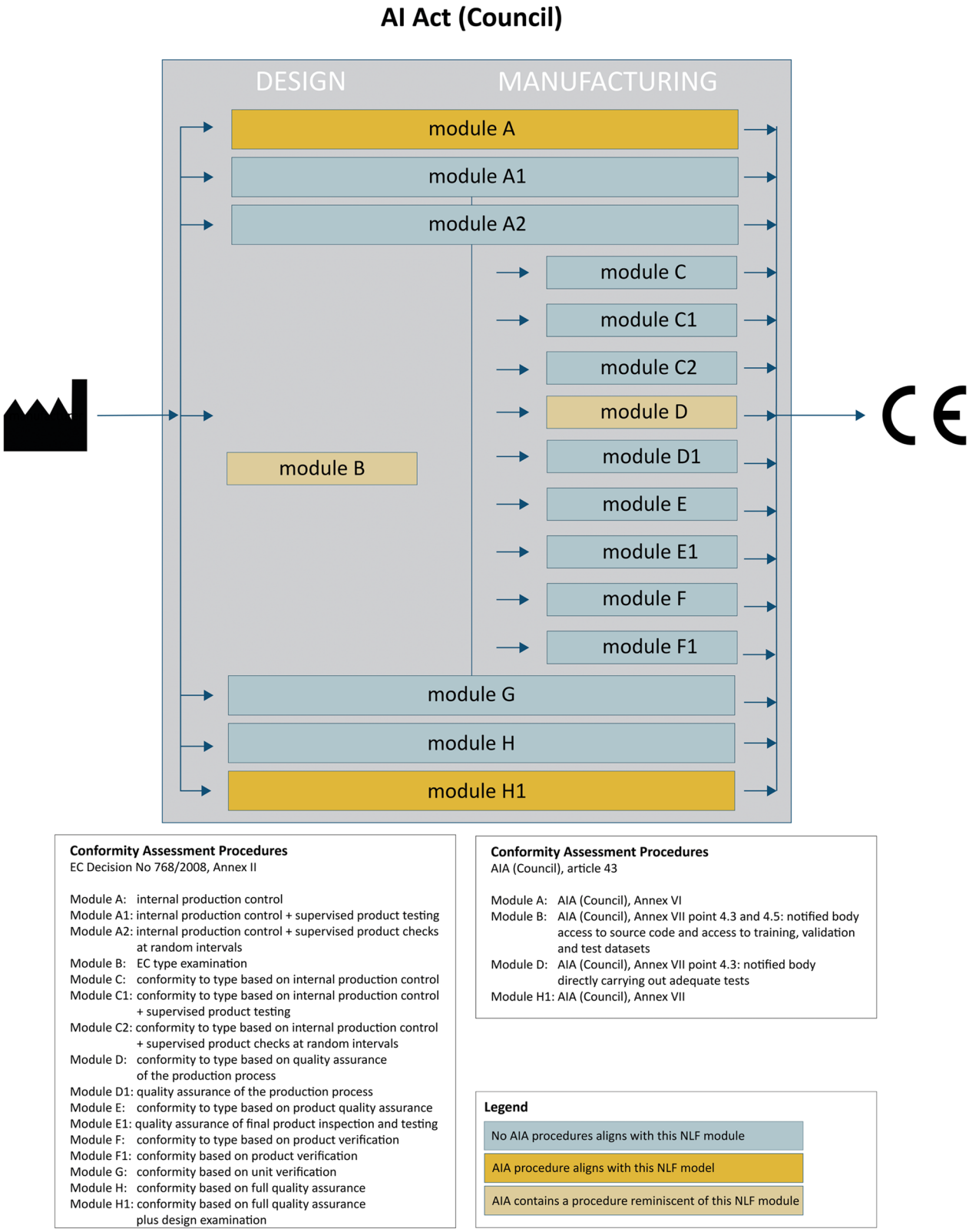

Figure 2 — Decision No 768/2008/EC (see [24]) conformity assessment procedures available in the EU AI Act (AIA), see [8], in consideration of access to source code, training, validation, and test data sets and test provisions.

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4.3.3 Conformity assessment modules following the EU AI Act Annex II Section A

According to Article 43(3) of the **EU AI Act (see [8])**, the following applies: *"For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, the provider shall follow the relevant conformity assessment as required under those legal acts. The requirements set out in Chapter 2 of this Title shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply."*

The following sections provide an overview of the conformity assessment modules available under sectorial legislation.

4.3.4 Conformity assessment modules under sectorial legislation

4.3.4.1 Conformity assessment modules of the Machinery Regulation

Machinery Regulation 2023/1230 (MR) (see lays down requirements for the safety of, among others, machinery. Depending on whether the machinery (or other items in scope of the regulation) is referenced in Annex I of the regulation, Module A, B or H apply (see Figure 3).

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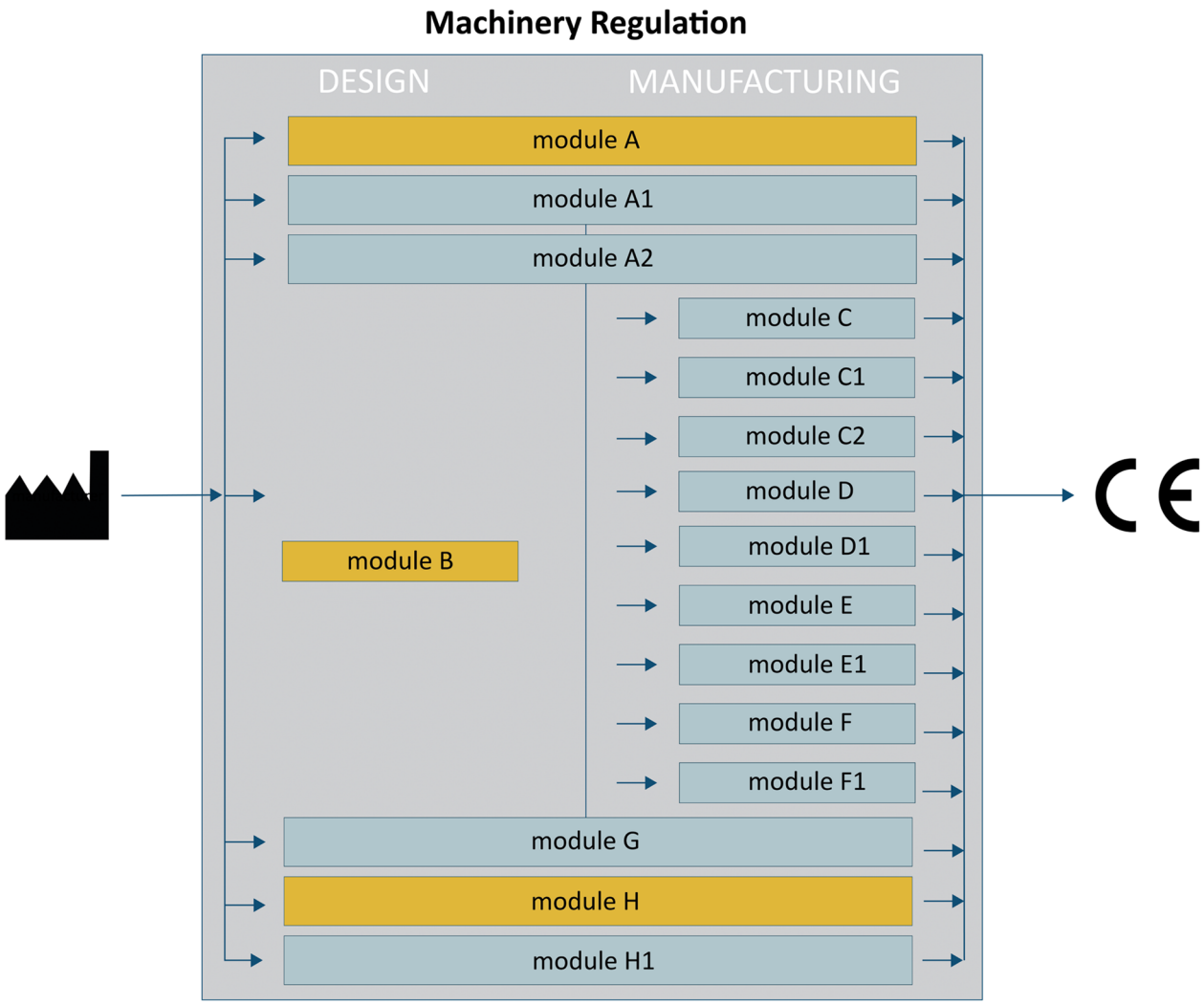

Conformity Assessment Procedures
EC Decision No 768/2008, Annex II

Module A: internal production control
Module A1: internal production control + supervised product testing
Module A2: internal production control + supervised product checks at random intervals
Module B: EC type examination
Module C: conformity to type based on internal production control
Module C1: conformity to type based on internal production control + supervised product testing
Module C2: conformity to type based on internal production control + supervised product checks at random intervals
Module D: conformity to type based on quality assurance of the production process
Module D1: quality assurance of the production process
Module E: conformity to type based on product quality assurance
Module E1: quality assurance of final product inspection and testing
Module F: conformity to type based on product verification
Module F1: conformity based on product verification
Module G: conformity based on unit verification
Module H: conformity based on full quality assurance
Module H1: conformity based on full quality assurance plus design examination

Conformity Assessment Procedures
Machinery Regulation 2023/1230, Article 21 and Article 22

Module A: Machinery not listed in Annex I
Module B: high-risk machinery listed in Annex I
Module H: high-risk machinery listed in Annex I

Legend

No MR procedures aligns with this NLF module
MR procedure aligns with this NLF model
MR contains a procedure reminiscent of this NLF module

Figure 3 — Decision No 768/2008/EC (see [24]) conformity assessment procedures available in Machinery Regulation 2023/1230

Documents
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