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**TRAINING ACADEMY**

**Beginner 2**

**Course 4.4**

STANDARDISATION  
TRAINING ACADEMY

Topic:

**THE ROLE OF  
CONFORMITY  
ASSESSMENT IN  
QUALITY  
INFRASTRUCTURE**

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## Module Objectives

After completing this module, you should be able to:

1. understand that, generally speaking, conformity assessment comprises testing, inspection, and certification that are used in all fields of investigation, innovation, process improvement, productivity, product development, product compliance, etc;
2. understand that the conclusion of the conformity assessment activity is a statement of conformity which should provide unequivocal identification of the object and the specified requirements with which the object has been found to conform; and
3. understand that products that have been found to conform to the specified requirements should have a mark of conformity, either as the supplier's trade mark, a certification mark, or a conformity mark required by legislation, such as the CE mark.

## Key Terms

accreditation body, attestation, certificate of conformity, certification, declaration of conformity, conformity assessment, Conformity Assessment Body (CAB), conformity assessment scheme, conformity assessment system, first-party conformity assessment activity, inspection, a mark of conformity, an object of conformity assessment, second-party conformity assessment activity, statement of conformity, testing, third-party conformity assessment activity

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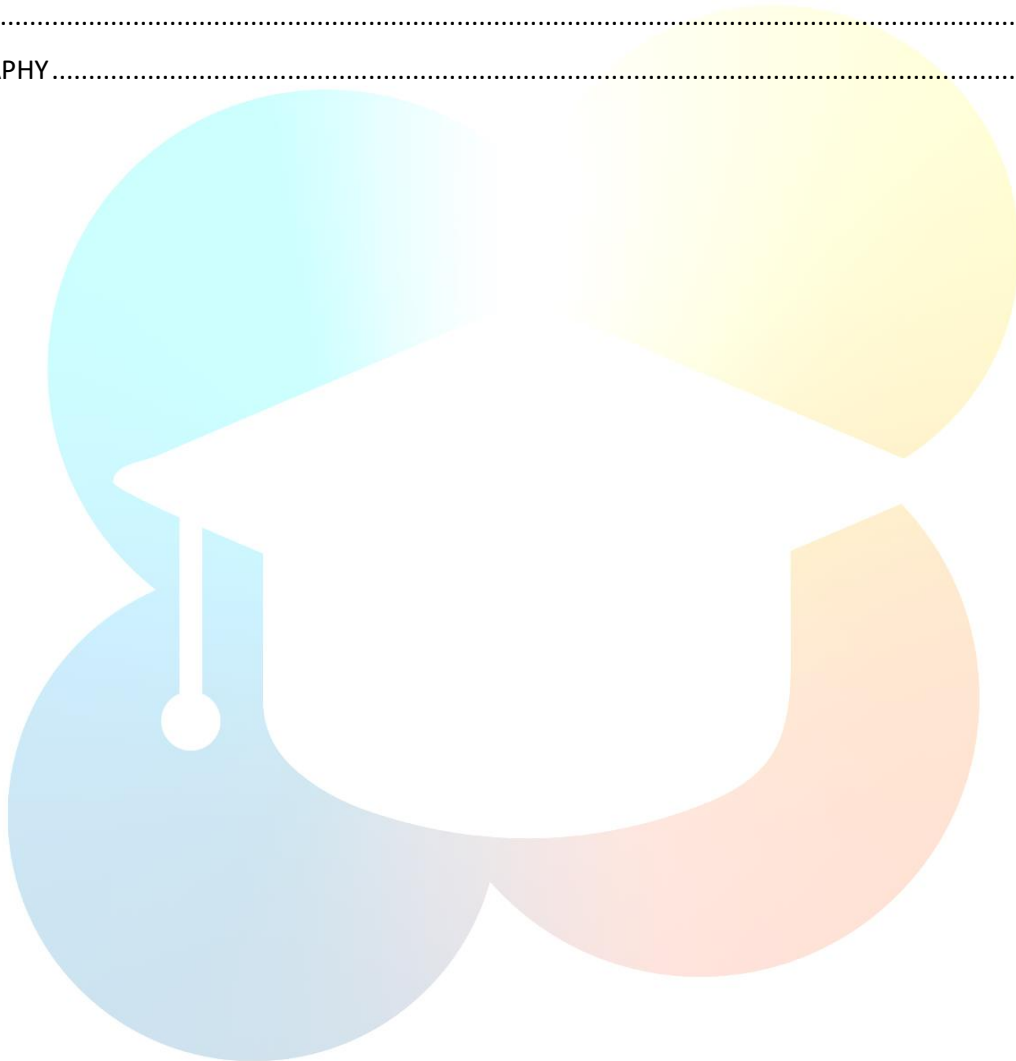


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# 1 CONFORMITY ASSESSMENT

According to ISO 17000:2020, **Conformity Assessment: Vocabulary and General Principles**, **conformity assessment** is defined as "a demonstration that specified requirements are fulfilled".<sup>1</sup> Accordingly, conformity assessment can also have a negative outcome, thereby demonstrating that the specified requirements are not fulfilled.<sup>2</sup> These specified requirements may be detailed or general and may be stated in normative documents, such as regulations, standards, and technical specifications.<sup>3</sup> Additionally, **the object of conformity assessment** is defined as "an entity to which these specified requirements apply (e.g. product, process, service, system, installation, project, data, design, material, claim, person, body or organisation, or any combination thereof)".<sup>4</sup> Similarly, **the first-party conformity assessment activity** is "conformity assessment activity that is performed by the person or organisation that provides or that is the object of conformity assessment (e.g. activities performed by providers, designers or owners of the object, investors in the object, and advertisers or promoters of the object)", **the second-party conformity assessment activity** is "conformity assessment activity that is performed by a person or organisation that has a user interest in the object of conformity assessment (e.g. purchasers or users of products, or potential customers seeking to rely on a supplier's management system, or organisations representing those interests, such as consumer advocacy organisations, regulators implementing legislation governing products and services for the protection of consumer and public interests, centralised government procurement organisations and private sector purchasing agents)", and **the third-party conformity assessment activity** is "conformity assessment activity that is performed by a person or organisation that is independent of the provider of the object of conformity assessment and has no user interest in the object of conformity assessment".<sup>5</sup> Given that **an accreditation body** is "an authoritative body that performs accreditation", a **conformity assessment body (CAB)** is "a body that performs conformity assessment activities, excluding accreditation".<sup>6</sup> Additionally, **the conformity assessment system** is defined as "a set of rules and procedures for the management of similar or related conformity assessment schemes" and **the conformity assessment scheme** is defined as "a set of rules and procedures that describes the objects of conformity assessment, identifies the specified requirements, and provides the methodology for performing conformity assessment activity".<sup>7</sup> Accordingly, the conformity assessment scheme may be managed within the conformity assessment system and may be operated at international, regional, national, sub-national, or industry levels.<sup>8</sup> Generally speaking, conformity assessment comprises testing, inspection, and certification "used in all fields

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<sup>1</sup> ISO/IEC. (2020). Conformity assessment — Vocabulary and general principles.

<sup>2</sup> Ibid.

<sup>3</sup> Ibid.

<sup>4</sup> Ibid.

<sup>5</sup> Ibid.





<sup>6</sup> Ibid.

<sup>7</sup> Ibid.

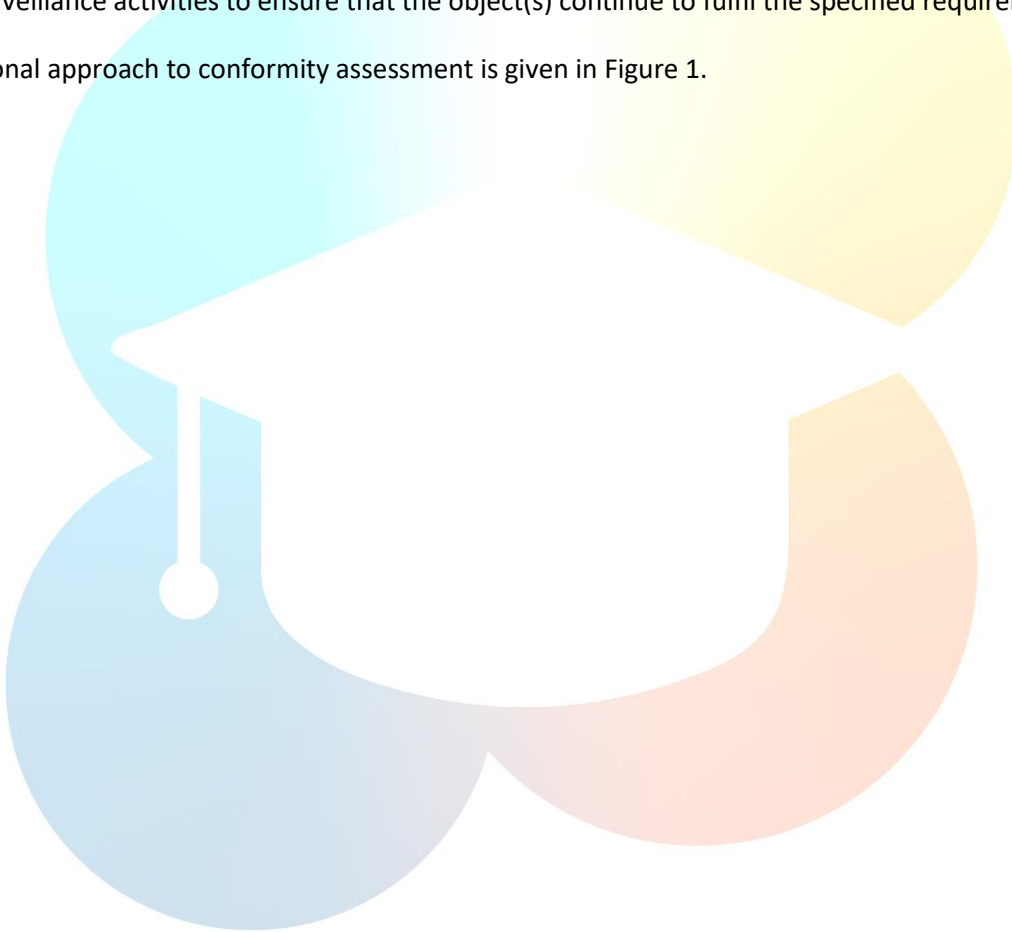
<sup>8</sup> Ibid.

of investigation, innovation, process improvement, productivity, product development, product compliance, etc.". <sup>9</sup>

The functional approach describes the following generic elements that are usually evident in any scheme: <sup>10</sup>

-  **Selection** of the object(s) of conformity assessment, the selection of the specified requirements which are to be assessed, and the selection of statistical sampling activities to be used (if applicable);
-  **Determination** of the specified characteristics (and the fulfilment of the specified requirements) of the object(s) of conformity assessment (or its sample) by using one or more determination methods (e.g. test, audit and/or examination);
-  **Review** of the relevant evidence collected during the determination stage, before making a **decision** on whether or not the object(s) of conformity assessment (or its sample) has been determined to fulfil the specified requirements, and a subsequent **attestation** of them (based on this decision);
-  **Surveillance** of the object(s) of conformity assessment, including the frequency and the extent of surveillance activities to ensure that the object(s) continue to fulfil the specified requirements.

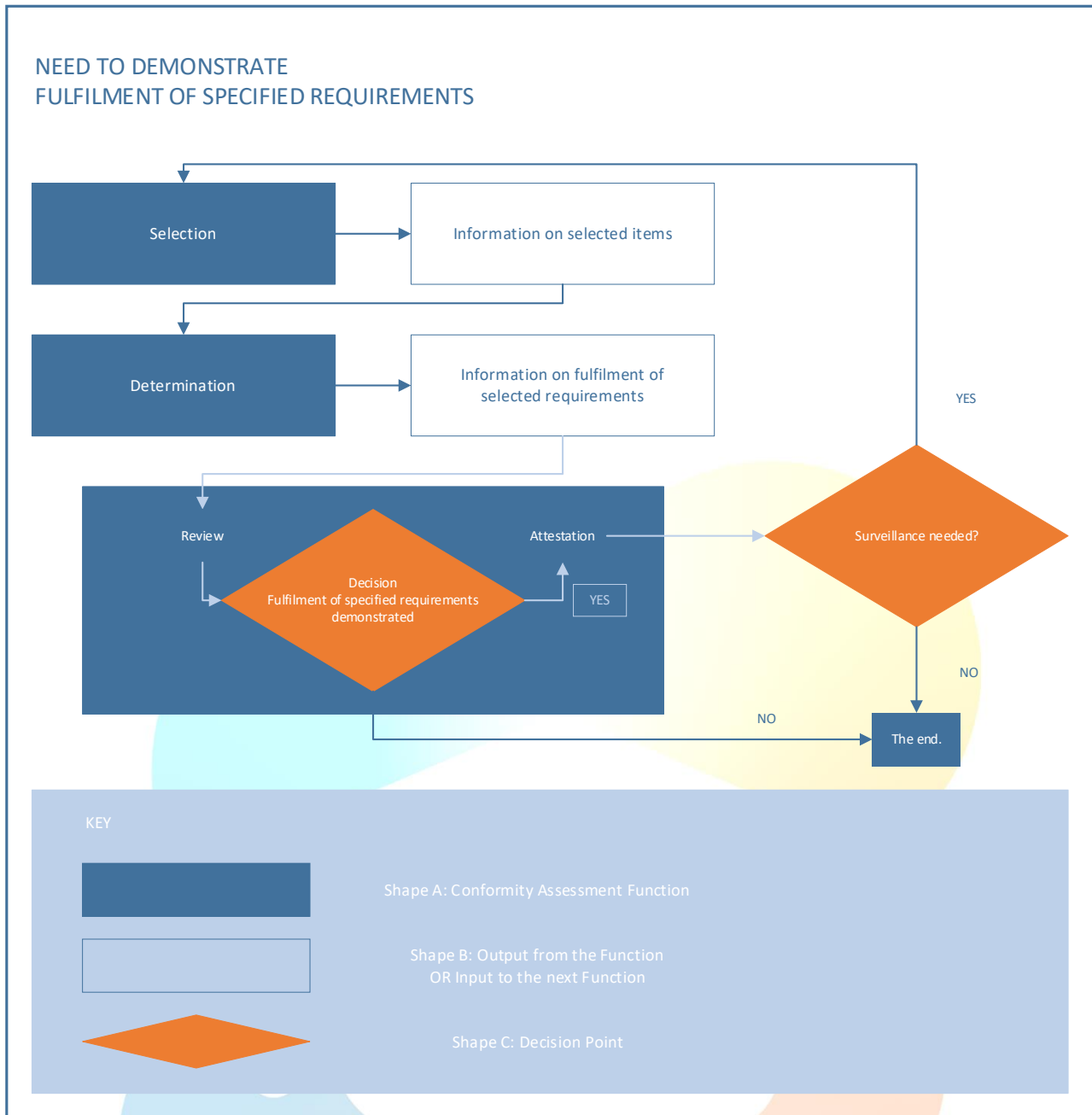
The functional approach to conformity assessment is given in Figure 1.



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<sup>9</sup> Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on 20.02.2025. Retrieved from: <https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQIToolkitReport.pdf>, pp. 109.

<sup>10</sup> ISO/IEC. (2009). Conformity assessment — Guidance for drafting normative documents.



**Fig. 1. Functional Approach to Conformity Assessment** <sup>11</sup>

<sup>11</sup> ISO/UNIDO. (2023). Building trust. The Conformity Assessment Toolbox. Accessed on 20.02.2025. Retrieved from: [https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco\\_building-trust.pdf](https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_building-trust.pdf), pp. 58.



## 1.1 TESTING

According to **ISO 17000:2020, Conformity Assessment – Vocabulary and General Principles**, testing is defined as "the determination of one or more characteristics of an object of conformity assessment, according to a procedure".<sup>12</sup> The procedure may aim to "control variables within testing as a contribution to the accuracy or reliability of the results".<sup>13</sup> The results of testing may be seen as specified units or objective comparisons with agreed references.<sup>14</sup> The outputs of testing may be a test report or a test certificate.<sup>15</sup> These outputs may comprise comments about the results of testing and the level of the fulfilment of the specified requirements.<sup>16</sup> The scope of testing may be extensive, "ranging from mechanical, electrical, metallurgical and civil engineering, and biological and chemical sciences to food technology, fibre technology, etc.". <sup>17</sup>

## 1.2 INSPECTION

According to **ISO 17000:2020, Conformity Assessment – Vocabulary and General Principles**, inspection is defined as "the examination of an object of conformity assessment and determination of its conformity with detailed requirements or, on the basis of professional judgement, with general requirements".<sup>18</sup> Such an examination consists of information gathering (which could comprise testing and measuring), direct and indirect observations (comprising the conditions), and forming a judgment on compliance with requirements.<sup>19</sup> Such a judgement is crucial which is why "the inspection could be prone to some variability of outcome".<sup>20</sup> To overcome this limitation, inspectors must be trained for the sectors in which they are planning to work.<sup>21</sup>

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<sup>12</sup> ISO/IEC. (2020). Conformity assessment — Vocabulary and general principles.

<sup>13</sup> Ibid.

<sup>14</sup> Ibid.

<sup>15</sup> Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on 20.02.2025. Retrieved from: <https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQIToolkitReport.pdf>, pp. 114.

<sup>16</sup> ISO/IEC. (2020). Conformity assessment — Vocabulary and general principles.

<sup>17</sup> Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on 20.02.2025. Retrieved from: <https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQIToolkitReport.pdf>, pp. 114.

<sup>18</sup> ISO/IEC. (2020). Conformity assessment — Vocabulary and general principles.

<sup>19</sup> Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on 20.02.2025. Retrieved from: <https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQIToolkitReport.pdf>, pp. 109.

<sup>20</sup> Ibid.

<sup>21</sup> Ibid.





## 1.3 CERTIFICATION

According to **ISO 17000:2020, Conformity Assessment – Vocabulary and General Principles**, **certification** is defined as "a third-party attestation related to an object of conformity assessment, excluding accreditation", whereas **attestation** is defined as "the issue of a statement, based on a decision, that fulfilment of specified requirements has been demonstrated".<sup>22</sup> A resulting statement, also known as **a statement of conformity** aims to "convey the assurance that the specified requirements have been fulfilled" but such an assurance does not provide any contractual or other legal guarantees.<sup>23</sup> Accordingly, first-party attestation and third-party attestation are distinguished by the terms declaration, certification, and accreditation, but there is no adequate term applicable to a second-party attestation.<sup>24</sup> Additionally, certification as such applies to all conformity assessment entities except for conformity assessment bodies to which the accreditation applies.

<sup>25</sup>

## 1.4 STATEMENT OF CONFORMITY

The conclusion of conformity assessment is **a statement of conformity** which may take several forms:<sup>26</sup>

-  a statement of conformity issued by a 1st party, e.g. the supplier of a product or a 2nd party, e.g. the purchaser, is called **a declaration of conformity**; and
-  a statement of conformity issued by a 3rd party, e.g. a person or organisation that is independent of the provider of the object of conformity assessment and has no user interest in the object of conformity assessment is called **a certificate of conformity**.

<sup>22</sup> ISO/IEC. (2020). Conformity assessment — Vocabulary and general principles.

<sup>23</sup> Ibid.

<sup>24</sup> Ibid.

<sup>25</sup> Ibid.

<sup>26</sup> ISO/UNIDO. (2023). Building trust. The Conformity Assessment Toolbox. Accessed on 20.02.2025. Retrieved from: [https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco\\_building-trust.pdf](https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_building-trust.pdf), pp. 42.

## 1.5 MARK OF CONFORMITY

Whichever form it takes, the statement "should provide unequivocal identification of the object and of the specified requirements with which the object has been found to conform".<sup>27</sup> Finally, products that have been found to conform to the specified requirements should have a **mark of conformity**, "either as the supplier's trade mark, a certification mark by a certification body or a mark required by legislation, such as the CE mark".<sup>28</sup>

## 2 THE EU CONFORMITY ASSESSMENT LEGISLATION

According to the **European Commission's Blue Guide on the implementation of EU Product Rules (2022)**, **conformity assessment** is "the process carried out by the manufacturer of demonstrating whether specified requirements relating to a product have been fulfilled".<sup>29</sup> A product is subjected to conformity assessment both during the design and production phases.<sup>30</sup> Conformity assessment always remains the responsibility of the manufacturer, so if a manufacturer subcontracts design or production, he/she still remains responsible for conformity assessment.<sup>31</sup> A manufacturer chooses from conformity assessment modules/procedures (laid down under Decision No 768/2008/EC).<sup>32</sup> Some modules cover both phases (e.g. module A) and sometimes distinct modules are used for each phase (e.g. module B (the EU-type examination) is always followed by some of the modules by which the conformity of the products to the EU-type is demonstrated).<sup>33</sup>

An overview of the EU conformity assessment modules/procedures is given in **Fig. 1**.

<sup>27</sup> Ibid.

<sup>28</sup> Ibid., pp. 43.

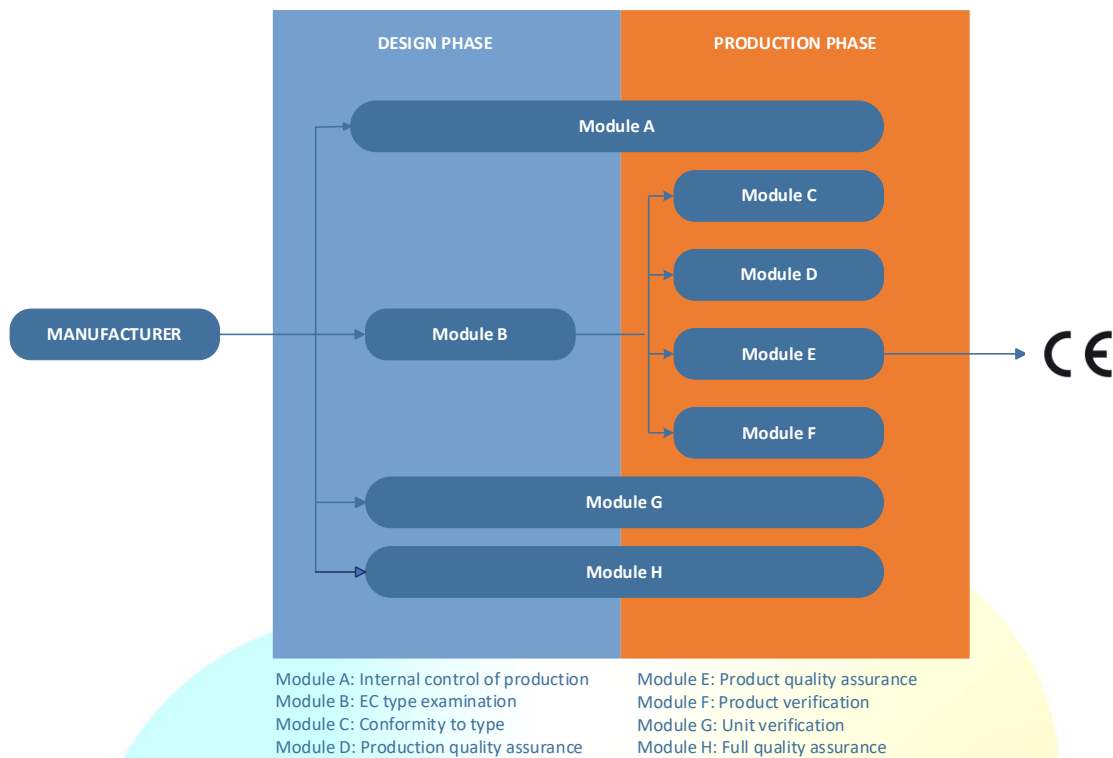
<sup>29</sup> EC. (2022). The 'Blue Guide' on the implementation of EU product rules 2022 (Text with EEA relevance) (2022/C 247/01). Official Journal of the European Union, vol. 65. Accessed on 20.02.2025. Retrieved from: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2022:247:FULL&from=EN>, pp. 70.

<sup>30</sup> Ibid.

<sup>31</sup> Ibid.

<sup>32</sup> Ibid.

<sup>33</sup> Ibid.



**Fig. 1.** An overview of the EU conformity assessment modules/procedures<sup>34</sup>

Conformity assessment must not be confused with **market surveillance**, which consists of controls by the market surveillance authorities after the product has been placed on the market.<sup>35</sup> These techniques are equally necessary to ensure the protection of the public interests and the smooth functioning of the market.

<sup>36</sup>

*QI Diagnostics and Reforms Toolkit (Module 6)*, jointly developed by the World Bank Group and the National Metrology Institute of Germany, explores in detail the significance and applicability of conformity assessment, and may be accessed freely via the following link:

 <https://thedocs.worldbank.org/en/doc/106831553265334313-0090022019/original/Part2.Module6ConformityAssessment.pdf>

<sup>34</sup> Ibid., pp. 79.

<sup>35</sup> Ibid., pp. 70.

<sup>36</sup> Ibid., pp. 70.

## SUMMARY

According to **ISO 17000:2020, Conformity Assessment: Vocabulary and General Principles**, **conformity assessment** is defined as "a demonstration that specified requirements are fulfilled".<sup>37</sup> Accordingly, conformity assessment can also have a negative outcome, thereby demonstrating that the specified requirements are not fulfilled.<sup>38</sup> These specified requirements may be detailed or general and may be stated in normative documents, such as regulations, standards, and technical specifications.<sup>39</sup> Additionally, **the object of conformity assessment** is defined as "an entity to which these specified requirements apply (e.g. product, process, service, system, installation, project, data, design, material, claim, person, body or organisation, or any combination thereof)".<sup>40</sup> Similarly, **the first-party conformity assessment activity** is "conformity assessment activity that is performed by the person or organisation that provides or that is the object of conformity assessment (e.g. activities performed by providers, designers or owners of the object, investors in the object, and advertisers or promoters of the object)", **the second-party conformity assessment activity** is "conformity assessment activity that is performed by a person or organisation that has a user interest in the object of conformity assessment (e.g. purchasers or users of products, or potential customers seeking to rely on a supplier's management system, or organisations representing those interests, such as consumer advocacy organisations, regulators implementing legislation governing products and services for the protection of consumer and public interests, centralised government procurement organisations and private sector purchasing agents", and **the third-party conformity assessment activity** is "conformity assessment activity that is performed by a person or organisation that is independent of the provider of the object of conformity assessment and has no user interest in the object of conformity assessment".<sup>41</sup> Given that **an accreditation body** is "an authoritative body that performs accreditation", a **conformity assessment body (CAB)** is "a body that performs conformity assessment activities, excluding accreditation".<sup>42</sup> Additionally, **the conformity assessment system** is defined as "a set of rules and procedures for the management of similar or related conformity assessment schemes" and **the conformity assessment scheme** is defined as "a set of rules and procedures that describes the objects of conformity assessment, identifies the specified requirements, and provides the methodology for performing conformity assessment activity".<sup>43</sup> Accordingly, the conformity assessment scheme may be managed within the conformity assessment system and may be operated at international, regional, national, sub-national, or industry levels.<sup>44</sup> Generally speaking, conformity assessment comprises testing, inspection, and certification

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<sup>37</sup> ISO/IEC. (2020). Conformity assessment — Vocabulary and general principles.

<sup>38</sup> Ibid.

<sup>39</sup> Ibid.

<sup>40</sup> Ibid.

<sup>41</sup> Ibid.

<sup>42</sup> Ibid.

<sup>43</sup> Ibid.

<sup>44</sup> Ibid.

"used in all fields of investigation, innovation, process improvement, productivity, product development, product compliance, etc.". <sup>45</sup>



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<sup>45</sup> Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on 20.02.2025. Retrieved from: <https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQIToolkitReport.pdf>, pp. 109.

## GLOSSARY

### accreditation body

“an authoritative body that performs accreditation”<sup>46</sup>

### attestation

“the issue of a statement, based on a decision, that fulfilment of specified requirements has been demonstrated”<sup>47</sup>

### certificate of conformity

“a statement of conformity issued by a 3rd party”<sup>48</sup>

### certification

“a third-party attestation related to an object of conformity assessment, excluding accreditation”<sup>49</sup>

### declaration of conformity

“a statement of conformity issued by a 1st party”<sup>50</sup>

### conformity assessment

“a demonstration that specified requirements are fulfilled”<sup>51</sup>

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<sup>46</sup> ISO/IEC. (2020). Conformity assessment — Vocabulary and general principles.

<sup>47</sup> Ibid.

<sup>48</sup> ISO/UNIDO. (2023). Building trust. The Conformity Assessment Toolbox. Accessed on 20.02.2025. Retrieved from: [https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco\\_building-trust.pdf](https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_building-trust.pdf), pp. 42.

<sup>49</sup> ISO/IEC. (2020). Conformity assessment — Vocabulary and general principles.

<sup>50</sup> ISO/UNIDO. (2023). Building trust. The Conformity Assessment Toolbox. Accessed on 20.02.2025. Retrieved from: [https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco\\_building-trust.pdf](https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_building-trust.pdf), pp. 42.

<sup>51</sup> ISO/IEC. (2020). Conformity assessment — Vocabulary and general principles.

### **Conformity Assessment Body (CAB)**

“a body that performs conformity assessment activities, excluding accreditation”<sup>52</sup>

### **conformity assessment scheme**

“a set of rules and procedures that describes the objects of conformity assessment, identifies the specified requirements, and provides the methodology for performing conformity assessment activity”<sup>53</sup>

### **conformity assessment system**

“a set of rules and procedures for the management of similar or related conformity assessment schemes”<sup>54</sup>

### **first-party conformity assessment activity**

“conformity assessment activity that is performed by the person or organisation that provides or that is the object of conformity assessment (e.g. activities performed by providers, designers or owners of the object, investors in the object, and advertisers or promoters of the object)”<sup>55</sup>

### **inspection**

“the examination of an object of conformity assessment and determination of its conformity with detailed requirements or, on the basis of professional judgement, with general requirements”<sup>56</sup>

### **mark of conformity**

“the supplier’s trade mark, a certification mark controlled by a certification body or a conformity mark required by legislation, such as the CE mark”<sup>57</sup>

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<sup>52</sup> ISO/IEC. (2020). Conformity assessment — Vocabulary and general principles.

<sup>53</sup> Ibid.

<sup>54</sup> Ibid.

<sup>55</sup> Ibid.

<sup>56</sup> Ibid.

<sup>57</sup> ISO/UNIDO. (2023). Building trust. The Conformity Assessment Toolbox. Accessed on 20.02.2025. Retrieved from: [https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco\\_building-trust.pdf](https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_building-trust.pdf), pp. 43.



### **object of conformity assessment**

“an entity to which these specified requirements apply (e.g. product, process, service, system, installation, project, data, design, material, claim, person, body or organisation, or any combination thereof)”<sup>58</sup>

### **second-party conformity assessment activity**

“conformity assessment activity that is performed by a person or organisation that has a user interest in the object of conformity assessment (e.g. purchasers or users of products, or potential customers seeking to rely on a supplier's management system, or organisations representing those interests, such as consumer advocacy organisations, regulators implementing legislation governing products and services for the protection of consumer and public interests, centralised government procurement organisations and private sector purchasing agents)”<sup>59</sup>

### **statement of conformity**

aims to “convey the assurance that the specified requirements have been fulfilled”<sup>60</sup>

### **testing**

“the determination of one or more characteristics of an object of conformity assessment, according to a procedure”<sup>61</sup>

### **third-party conformity assessment activity**

“conformity assessment activity that is performed by a person or organisation that is independent of the provider of the object of conformity assessment and has no user interest in the object of conformity assessment”<sup>62</sup>

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<sup>58</sup> ISO/IEC. (2020). Conformity assessment — Vocabulary and general principles.

<sup>59</sup> Ibid.

<sup>60</sup> Ibid.

<sup>61</sup> Ibid.

<sup>62</sup> Ibid.

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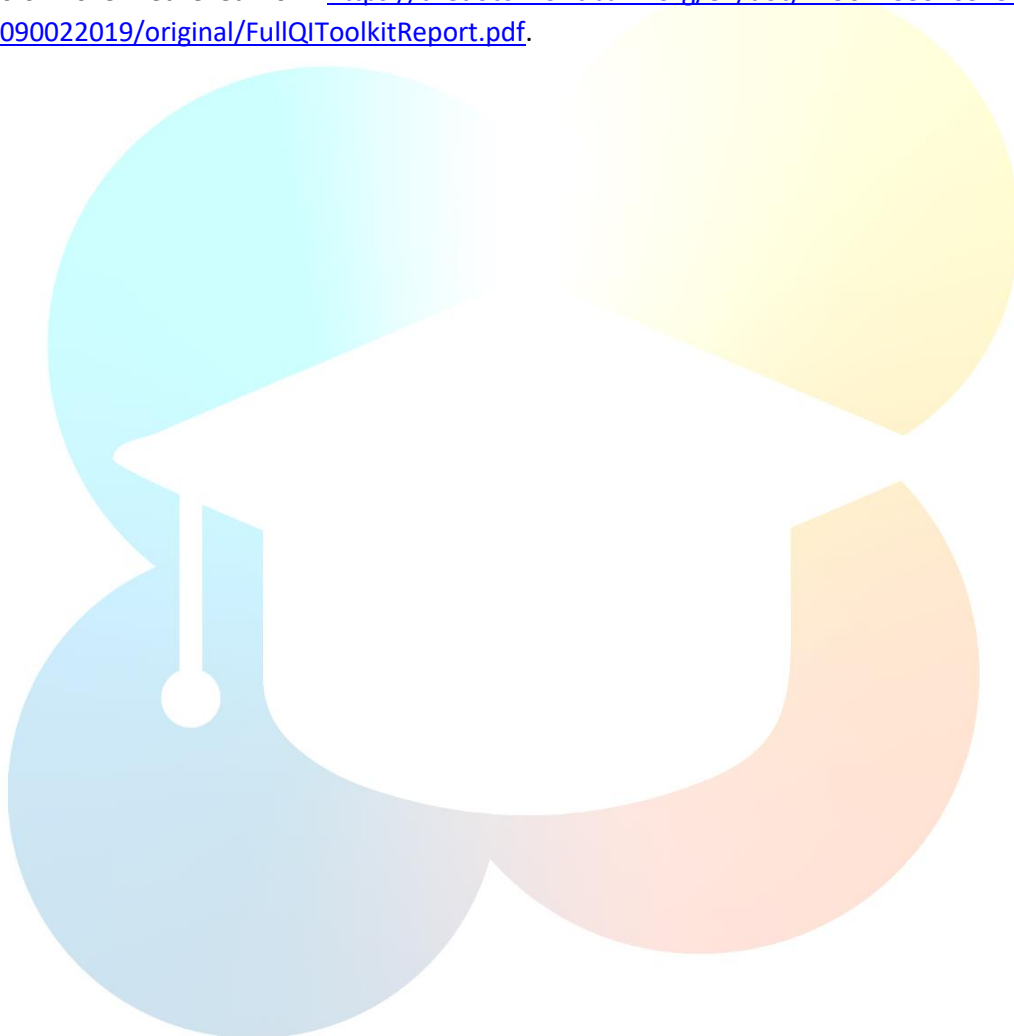
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