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TRAINING ACADEMY

Beginner 2

Course 4.5

STANDARDISATION TRAINING ACADEMY

Topic:

THE ROLE OF MARKET SURVEILLANCE IN QUALITY INFRASTRUCTURE

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Module Objectives

After completing this module, you should be able to:

1. understand that market surveillance shall be used as a basis for maintaining the validity of the statement of conformity or the mark of conformity;
2. understand that economic constraints usually lead to targeted market surveillance where risks are likely to be higher or noncompliance more common; and
3. understand that market surveillance via technical regulations has become one of the major issues hindering the movement of goods across borders and within countries.

Key Terms

CE mark, market surveillance, Regulation (EU) 2019/1020

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1 MARKET SURVEILLANCE

Market surveillance shall be seen as a continuous evolution of conformity assessment activities as a basis for maintaining the validity of the statement or the mark of conformity. [1] To ensure that market surveillance activities are carried out adequately, most countries establish regulatory authorities to carry out market surveillance. [2] Some countries will establish one or more regulatory authorities with specific mandates within each ministry. [3] Some countries will establish only four or five larger regulatory authorities within specific sectors (e.g. telecommunication services, transportation, building and construction, etc.). [4] Small countries may establish only one regional regulatory authority for all products falling within the scope of the technical regulations and market surveillance. [5] The choice will be determined by the political, environmental, and social customs, scarcity of economic resources, and the extent of the work done within market surveillance. [6]

Although surveillance activities should be conducted regularly, economic constraints usually lead to targeted surveillance where risks are likely to be higher or noncompliance to be found more common. [7] Subsequently, regulatory authorities must act accordingly to enforce conformity when nonconforming products are discovered. [8] This means that corrective action should depend on the degree of noncompliance and should follow the principle of proportionality. [9] Accordingly, differentiating between substantial and nonsubstantial noncompliance should be based on the sound judgment (e.g. small errors may be considered nonsubstantial, but noncompliance that may be deleterious to the health or safety of users must be considered substantial). [10]

Typical administrative sanctions against noncompliant products are given in **Fig. 1**.

[1] ISO/UNIDO. (2010). Building trust. The Conformity Assessment Toolbox. Accessed on October 27, 2022. Retrieved from: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_building-trust.pdf, pp. 44.
[2] Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on October 27, 2022. Retrieved from: https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQIToolkitReport.pdf, pp. 153.
[3] Ibid., pp. 153.
[4] Ibid., pp. 153.
[5] Ibid., pp. 153.
[6] Ibid., pp. 153.
[7] ISO/UNIDO. (2010). Building trust. The Conformity Assessment Toolbox. Accessed on October 27, 2022. Retrieved from: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_building-trust.pdf, pp. 45.
[8] Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on October 27, 2022. Retrieved from: https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQIToolkitReport.pdf, pp. 155.
[9] Ibid., pp. 155.
[10] Ibid., pp. 155.

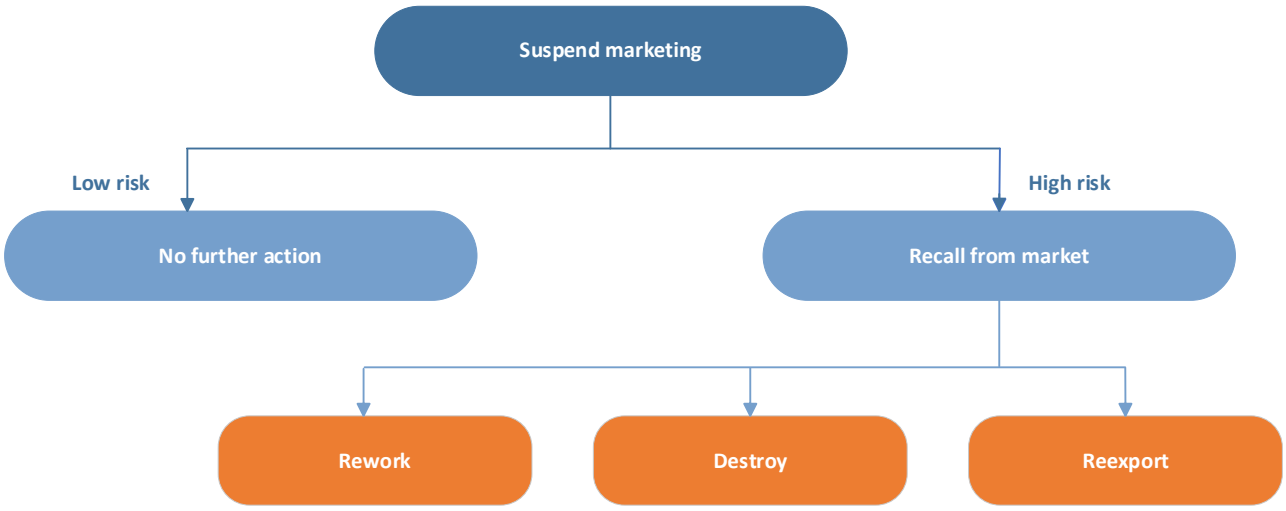

Fig. 1. Typical administrative sanctions against non-compliant products [11]

Market surveillance via technical regulations has become one of the major issues hindering the movement of goods across borders and within countries. [12] As technical regulations are developed by authorities at the national and subnational levels, coordination of their responsibilities (among each other and between them) and various standardisation, metrology, accreditation, or conformity assessment bodies has become crucial. [13]

Typical organisational relationships between QI and the regulatory authorities are given in **Fig. 2.**

[11] Ibid., pp. 155.
[12] Ibid., pp. 160.
[13] Ibid., pp. 160.

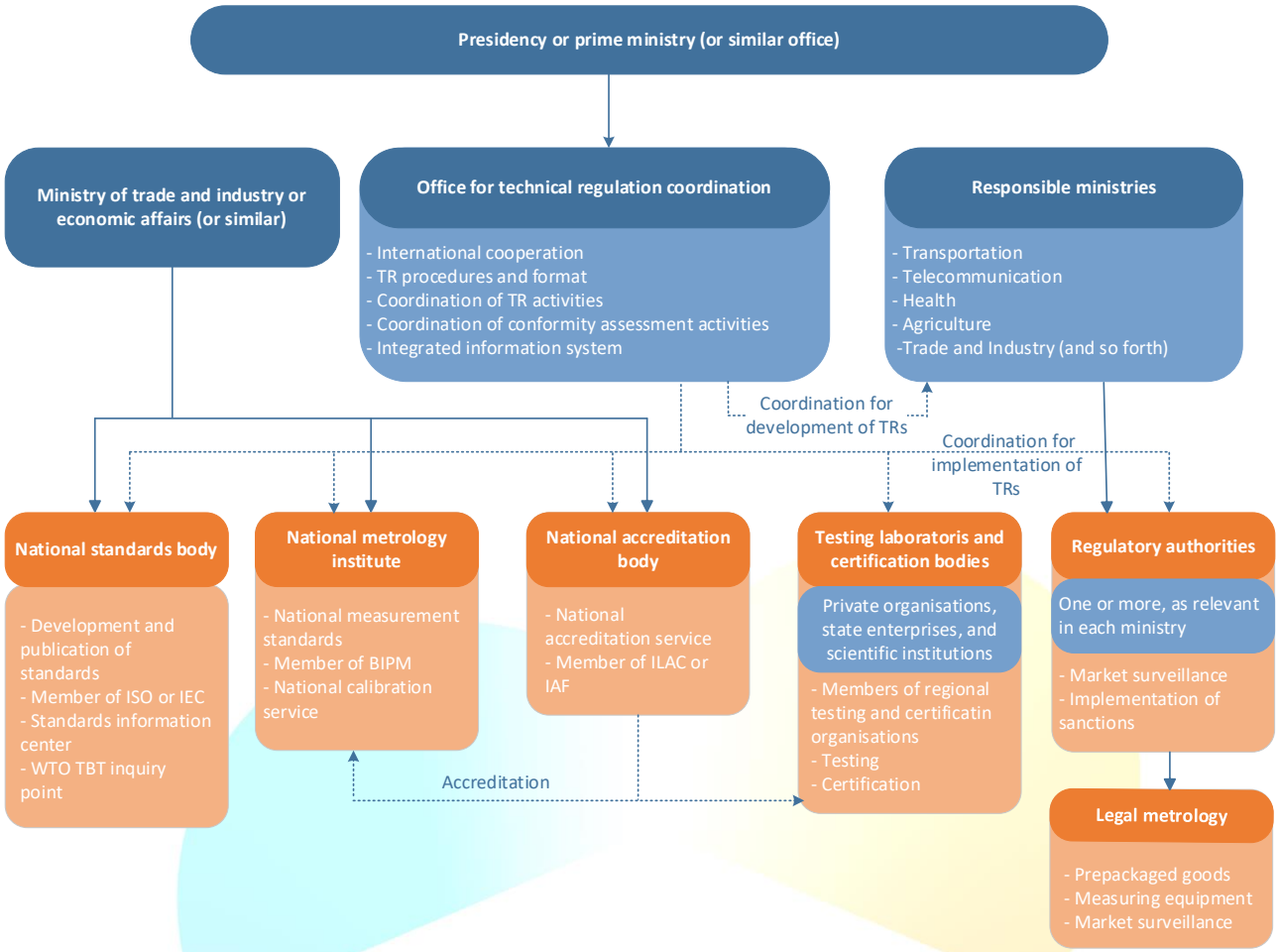

Fig. 2. Typical organisational relationships between QI and regulatory authorities [14]

QI Diagnostics and Reforms Toolkit (Module 7), jointly developed by the World Bank Group and the National Metrology Institute of Germany, explores in detail technical regulations (being legally binding, while standards compliance is voluntary) and market surveillance, and especially the WTO TBT Agreement, and may be accessed freely via the following link:

- https://thedocs.worldbank.org/en/doc/907541553265335870-0090022019/original/Part2.Module7TechnicalRegulation.pdf

[14] Racine, J.L. (2011). Harnessing Quality for Global Competitiveness in Eastern Europe and Central Asia. Washington, DC: World Bank., pp. 90.

1.1 The EU Market Surveillance Legislation

Aiming to guarantee the free movement of products within the EU, the framework for market surveillance established by the Regulation (EU) 2019/1020 ensures that products ''are compliant with the EU harmonisation legislation and therefore fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety in the workplace, protection of consumers, protection of the environment, public security and any other public interests protected by that legislation''. [15]

The EU market surveillance legislation guarantees: [16]

- clear and uniform rules applying to non-food products and economic operators,
- requirements to ensure that market surveillance can cope with the EU legislation,
- streamlined market surveillance procedures to control products within the EU, and
- tools to coordinate activities conducted by national surveillance bodies across the EU (e.g. discussion forums, ICTs databases, common market surveillance campaigns, etc.).

The framework for market surveillance established by the Regulation (EU) 2019/1020 ''should complement and strengthen existing provisions in the EU market surveillance harmonisation legislation related to ensuring compliance of products and the framework for cooperation with organisations representing economic operators or end-users, the market surveillance of products, and controls on those products entering the EU market''. [17]

Member States must establish adequate mechanisms and carry out activities to monitor the products that are available on the market or imported through both online and offline sales and distribution channels. [18] The main objective is to ensure that products have been designed and manufactured according to the EU harmonisation legislation requirements, marking and documentation requirements and that they have been adequately subjected to the necessary procedures. [19] If this is not the case, market surveillance authorities must require the relevant economic operators to take appropriate corrective actions to ensure compliance with the applicable requirements. [20] If economic operators fail to take corrective actions, market surveillance

[15] EU. (2019). Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance and compliance of products. Accessed on January 23, 2023. Retrieved from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1020

[16] EC. (2023). Market Surveillance for Products. Accessed on January 23, 2023. Retrieved from: https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/market-surveillance_en

[17] EU. (2019). Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance and compliance of products. Accessed on January 23, 2023. Retrieved from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1020., p. 2.

[18] EC. (2022). The 'Blue Guide' on the implementation of EU products rules 2022 (Text with EEA relevance) (2022/C 247/01). Official Journal of the European Union, vol. 65. Accessed on January 23, 2023. Retrieved from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2022:247:FULL&from=EN., pp. 105.

[19] Ibid., pp. 105.

[20] Ibid., pp. 105.

authorities should take appropriate measures to ensure that unsafe products or products which otherwise do not conform to applicable requirements are taken off the market and unscrupulous operators sanctioned (proportionate to infringements). [21]

To learn more about the EU market surveillance legislation, please visit the following link:

- https://commission.europa.eu/business-economy-euro/product-safety-and-requirements/product-safety/product-safety-and-market-surveillance_en

1.2 What is CE Mark?

The CE mark is a key indicator (but not proof) that products that are being placed on the EEA and Turkish market are in conformance with the requirements laid down by the EU legislation whether they are manufactured in the EEA, in Turkey, or in another country. [22] The EAA Member States shall not restrict the market placement of CE-marked products unless such restrictions can be justified due to the evidence of the product's nonconformity (this applies to products that are made in third countries and are sold in the EEA). [23] The CE mark does not indicate that a product was made in the EU and it does not serve commercial purposes, rather it indicates that products were subjected to a conformity assessment process and are declared by the manufacturer to be in conformance with the requirements laid down by the EU legislation. [24] The CE mark is affixed only by the manufacturer (or by his authorised representative) who, by affixing the CE mark, declares on his sole responsibility that the product conforms to all of the applicable requirements laid down by the EU legislative (and that adequate conformity assessment activities have been completed). [25]

The CE mark must take the form below (see Figure 3).

Note: If the CE mark shall be reduced/enlarged, the proportions must be respected. [26]

[21] Ibid., pp. 105.
[22] Ibid., pp. 64.
[23] Ibid., pp. 64.
[24] Ibid., pp. 64.
[25] Ibid., pp. 65.
[26] Ibid., pp. 65.

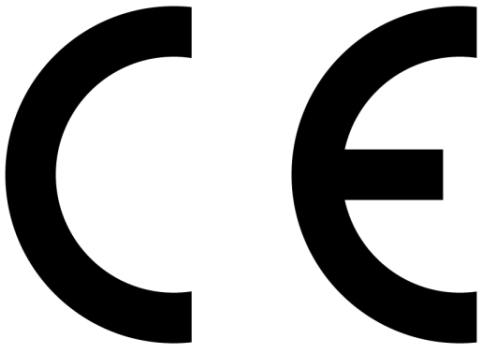

Fig. 3. CE mark [27]

To learn more about CE marking, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726(02)&from=BG
- https://europa.eu/youreurope/business/product-requirements/labels-markings/ce-marking/index_en.htm
- https://single-market-economy.ec.europa.eu/single-market/ce-marking_en

Not all products must have the CE mark. [28] The obligation to affix the CE mark applies to all products within the scope of legislative acts providing for its affixing, and which are being placed on the EU market, and it is forbidden to affix the CE mark on the other products. [29] Sometimes, a CE-marked product shall be incorporated as a part of another CE-marked product (in this case two CE marks may be found on a product). [30]

[27] EC. (2022). Internal Market, Industry, Entrepreneurship and SMEs. Accessed on January 23, 2023. Retrieved from: https://single-market-economy.ec.europa.eu/single-market/ce-marking_en

[28] EC. (2022). The 'Blue Guide' on the implementation of EU products rules 2022 (Text with EEA relevance) (2022/C 247/01). Official Journal of the European Union, vol. 65. Accessed on January 23, 2023. Retrieved from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2022:247:FULL&from=EN, pp. 67.

[29] Ibid., pp. 67.

[30] Ibid., pp. 67.

1.3 Scope of the Guide

Generally, CE marking shall be affixed on: [31]

Active implantable medical devices (Regulation (EU) 2017/745)

As a first step, you need to verify whether your product falls within the definition of an active implantable medical device in accordance with Article 1 paragraph 2a) to c) of Directive 90/385/EEC where the term 'active medical device' is also defined. For a definition of 'implantable device' see Annex IX, section I.1.2 of Directive 93/42/EEC on medical devices. Second, you need to verify that none of the exclusion clauses of Article 1 paragraph 3 to 6 is applicable. If all these conditions are fulfilled, the Directive 90/385/EEC applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20170505
- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31990L0385
- https://health.ec.europa.eu/medical-devices-sector/directives_en

Appliances burning gaseous fuels (Regulation (EU) 2016/426)

If your product falls within appliances burning gaseous fuels, Regulation (EU) 2016/426 applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0426
- https://op.europa.eu/en/publication-detail/-/publication/dc6c26dd-aafb-45b1-80fb-9605c25d5d21
- https://single-market-economy.ec.europa.eu/sectors/pressure-equipment-and-gas-appliances/gas-appliances-sector/gas-appliances-regulation_en

[31] EC. (2022). Internal Market, Industry, Entrepreneurship and SMEs. Accessed on January 23, 2023. Retrieved from: https://single-market-economy.ec.europa.eu/single-market/ce-marking/manufacturers_en

Cableway installations (Regulation (EU) 2016/424)

If your product falls within cableway installations, Regulation (EU) 2016/424 applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/eli/reg/2016/424/oj
- https://single-market-economy.ec.europa.eu/sectors/mechanical-engineering/cableways_en
- https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/cableway-installations_en

Construction products (Regulation (EU) 2011/305)

If your product falls within construction products, Regulation (EU) 2011/305 applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011R0305
- https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=LEGISSUM:mi0078&from=EN
- https://ec.europa.eu/docsroom/documents/45224
- https://single-market-economy.ec.europa.eu/sectors/construction/construction-products-regulation-cpr/review_en
- https://audiovisual.ec.europa.eu/en/video/I-088654

Eco-design for energy-related products (Directive 2009/125/EC)

If your product falls within energy-related products, Directive 2009/125/EC applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009L0125

- https://single-market-economy.ec.europa.eu/industry/sustainability/sustainable-product-policy-ecodesign_en
- https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/ecodesign_en

Electromagnetic compatibility (Directive 2014/30/EU)

If your product falls within the equipment encompassing electrical/electronic appliances, systems and installations, Directive 2014/30/EU applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1461936830934&uri=CELEX:32014L0030
- https://single-market-economy.ec.europa.eu/sectors/electrical-and-electronic-engineering-industries-eei/electromagnetic-compatibility-emc-directive_en
- https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/electromagnetic-compatibility-emc_en

Equipment and protective systems intended for use in potentially explosive atmospheres (Directive 2014/34/EU)

If your product falls within the equipment and protective systems for potentially explosive atmospheres, Directive 2014/34/EU applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0034
- https://single-market-economy.ec.europa.eu/sectors/mechanical-engineering/equipment-potentially-explosive-atmospheres-atex_en
- https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/equipment-explosive-atmospheres-atex_en

Explosives for civil uses (Directive 2014/28/EU)

If your products fall within explosives for civil use, Directive 2014/28/EU applies.

To learn more about the sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014L0028
- https://single-market-economy.ec.europa.eu/sectors/chemicals/chemicals-legislation_en
- https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/explosives-civil-uses_en

Hot water boilers (Directive 92/42/EEC)

If your products fall within hot water boilers, Directive 92/42/EEC applies.

To learn more about the sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31992L0042
- https://op.europa.eu/en/publication-detail/-/publication/8e650177-8e71-4299-ba38-9eb259aa16d7
- https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/ecodesign-boilers_en

In vitro diagnostic medical devices (Directive 98/79/EC to be replaced by Regulation (EU) 2017/746 as of 26 May 2022)

As a first step, you need to verify whether your product falls within the definition of an in vitro diagnostic medical device (IVD) in accordance with Article 1 paragraphs 2a), 2b) and 2c) of Directive 98/79/EC. Second, you need to verify that none of the exclusion clauses given in Article 1 are applicable. If all these conditions are fulfilled, Directive 98/79/EC applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0746-20170505
- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31998L0079
- https://health.ec.europa.eu/medical-devices-sector/overview_en
- https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en

Lifts (Directive 2014/33/EU)

If your product falls within lifts, Directive 2014/33/EU applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1461157794855&uri=CELEX:32014L0033
- https://single-market-economy.ec.europa.eu/sectors/mechanical-engineering/lifts_en

Low voltage (Directive 2014/35/EU)

If your product falls within the low voltage electrical equipment, Directive 2014/35/EU applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0035
- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0035
- https://single-market-economy.ec.europa.eu/sectors/electrical-and-electronic-engineering-industries-eei/low-voltage-directive-lvd_en

Machinery (Directive 2006/42/EC)

If your product falls within the machinery, the Directive 2006/42/EC applies.

To learn more about this sector, please visit the following link:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006L0042-20091215

Measuring instruments (Directive 2014/32/EU)

If your product falls within measuring instruments, Directive 2014/32/EU applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0032
- https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/measuring-instruments-mid_en
- https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/legal-metrology/measuring-instruments_en

Medical devices (Regulation (EU) 2017/745

As a first step, you need to verify whether your product falls within the definition of a medical device in accordance with Article 1 paragraph 2a) of Directive 93/42/EEC. Second, you need to exclude that your product falls within the definition of an active implantable medical device (Directive 90/385/EEC) or an in vitro diagnostic medical device (Directive 98/79/EC). Finally, you must verify that no other exclusion clause contained in the first Article of Directive 93/42/EEC is applicable. If all these conditions are fulfilled, Directive 93/42/EEC applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31993L0042
- https://health.ec.europa.eu/medical-devices-sector/directives_en

Noise emission in the environment (Directive 2000/14/EC)

If your product falls within the construction/gardening equipment, Directive 2000/14/EC applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:32000L0014
- https://single-market-economy.ec.europa.eu/sectors/mechanical-engineering/noise-emission-outdoor-equipment_en

Non-automatic weighing instruments (Directive 2014/31/EU)

If your product falls within non-automatic weighing instruments, Directive 2014/31/EU applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0031
- https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/legal-metrology/measuring-instruments_en
- https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/legal-metrology/measuring-instruments/measuring-instruments-guidance-documents_en

Personal protective equipment (Regulation (EU) 2016/425)

If your product falls within the personal protective equipment, Regulation (EU) 2016/425 applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0425
- https://single-market-economy.ec.europa.eu/sectors/mechanical-engineering/personal-protective-equipment-ppe_en

Pressure equipment (Directive 2014/68/EU)

If your product falls within the pressure equipment, Directive 2014/68/EU applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.189.01.0164.01.ENG
- https://single-market-economy.ec.europa.eu/sectors/pressure-equipment-and-gas-appliances/pressure-equipment-sector_en

Pyrotechnics (Directive 2013/29/EU)

If your product falls within the pyrotechnics, Directive 2013/29/EU applies.

To learn more about this sector, please visit the following links:

- http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013L0029&locale=en
- https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards/pyrotechnic-articles_en

Radio equipment (Directive 2014/53/EU)

If your product falls within the radio equipment, Directive 2014/53/EU applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0053
- https://single-market-economy.ec.europa.eu/sectors/electrical-and-electronic-engineering-industries-eei/radio-equipment-directive-red_en

Recreational craft (Directive 2013/53/EU)

If your product falls within the recreational craft, Directive 2013/53/EU applies.

To learn more about this sector, please visit the following links:

- http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013L0053&locale=en
- https://single-market-economy.ec.europa.eu/sectors/maritime-industries/recreational-craft-sector_en
- https://webgate.ec.europa.eu/ewcms/growth/single-market-and-standards/european-standards/harmonised-standards/recreational-craft_en

Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) (Directive 2011/65/EU)

If your product use hazardous substances in electrical and electronic equipment, Directive 2013/53/EU applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02011L0065-20160715
- https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive_en
- https://environment.ec.europa.eu/topics/waste-and-recycling/waste-electrical-and-electronic-equipment-weee_en

Safety of toys (Directive 2009/48/EC)

If your product falls within toys, Directive (2009/48/EC) applies.

To learn more about this sector, please visit the following links:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009L0048
- https://single-market-economy.ec.europa.eu/sectors/toys/toy-safety_en
- https://single-market-economy.ec.europa.eu/sectors/toys/toy-safety/guidance_en

Simple pressure vessels (Directive 2014/29/EU)

If your product falls within simple pressure vessels, Directive 2014/29/EU applies.

To learn more about this sector, please visit the following links:

- http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0029
- https://single-market-economy.ec.europa.eu/sectors/pressure-equipment-and-gas-appliances/pressure-equipment-sector_en

Fertilising Products (Regulation (EU) 2019/1009)

If your product falls within fertilising products, Regulation (EU) 2019/1009 applies.

To learn more about this sector, please visit the following link:

- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32019R1009

SUMMARY

Market surveillance shall be seen as a continuous evolution of conformity assessment activities as a basis for maintaining the validity of the statement or the mark of conformity. [32] To ensure that market surveillance activities are carried out adequately, most countries establish regulatory authorities to carry out market surveillance. [33] Some countries will establish one or more regulatory authorities with specific mandates within each ministry. [34] Some countries will establish only four or five larger regulatory authorities within specific sectors (e.g. telecommunication services, transportation, building and construction, etc.). [35] Small countries may establish only one regional regulatory authority for all products falling within the scope of the technical regulations/market surveillance. [36] The choice will be determined by the political, environmental, and social customs, scarcity of economic resources, and the extent of work done within market surveillance. [37] Although surveillance activities should be conducted regularly, economic constraints usually lead to targeted surveillance where risks are likely to be higher or noncompliance to be found more common. [38] Subsequently, regulatory authorities must act accordingly to enforce conformity when nonconforming products are discovered. [39] This means that corrective action should depend on the degree of noncompliance and should follow the principle of proportionality. [40] Accordingly, differentiating between substantial and nonsubstantial noncompliance should be based on the sound judgment (e.g. small errors may be considered nonsubstantial, but noncompliance that may be deleterious to the health or safety of users must be considered substantial). [41]

[32] ISO/UNIDO. (2010). Building trust. The Conformity Assessment Toolbox. Accessed on October 27, 2022. Retrieved from: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_building-trust.pdf, pp. 44.
[33] Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on October 27, 2022. Retrieved from: https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQIToolkitReport.pdf, pp. 153.
[34] Ibid., pp. 153.
[35] Ibid., pp. 153.
[36] Ibid., pp. 153.
[37] Ibid., pp. 153.
[38] ISO/UNIDO. (2010). Building trust. The Conformity Assessment Toolbox. Accessed on October 27, 2022. Retrieved from: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/casco_building-trust.pdf, pp. 45.
[39] Kellerman, M. (2019). Ensuring Quality to Gain Access to Global Markets (A Reform Toolkit). Accessed on October 27, 2022. Retrieved from: https://thedocs.worldbank.org/en/doc/249621553265195570-0090022019/original/FullQIToolkitReport.pdf, pp. 155.
[40] Ibid., pp. 155.
[41] Ibid., pp. 155.

GLOSSARY

CE mark

a key indicator (but not proof) that products that are being placed on the EEA and Turkish market are in conformance with the requirements laid down by the EU legislation whether they are manufactured in the EEA, in Turkey, or in another country. [42] The CE mark does not indicate that a product was made in the EU and it does not serve commercial purposes. [43] The CE mark indicates that products that are being placed on the EEA and Turkish markets were subjected to a whole conformity assessment process and are declared by the manufacturer to be in conformance with the requirements laid down by the EU legislation. [44]

market surveillance

''aims at ensuring that products fulfil the applicable requirements providing a high level of protection of public interests, such as health and safety in general, health and safety in the workplace, the protection of consumers, of the environment and of public security and any other public interest protected by the EU legislation'' [45]

Regulation (EU) 2019/1020

ensures that products ''are compliant with the EU harmonisation legislation and therefore fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety in the workplace, protection of consumers, protection of the environment, public security and any other public interests protected by that legislation'' [46]

[42] EC. (2022). The 'Blue Guide' on the implementation of EU products rules 2022 (Text with EEA relevance) (2022/C 247/01). Official Journal of the European Union, vol. 65. Accessed on January 23, 2023. Retrieved from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2022:247:FULL&from=EN

[43] Ibid.

[44] Ibid.

[45] Ibid.

[46] EU. (2019). Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance and compliance of products. Accessed on January 23, 2023. Retrieved from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1020

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