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REGULATION

From the Ministry of Industry and Technology:

MACHINERY SAFETY REGULATION
(2023/1230/EU)

PART ONE
Introductory Provisions

Purpose

ARTICLE 1—(1) The purpose of this Regulation is to establish health and safety requirements for the design and manufacture of machinery, related products, and partly completed machinery, and to regulate the rules regarding the free movement of products within its scope.

Scope

ARTICLE 2—(1) This Regulation covers machinery and the related products listed below:

a) Interchangeable equipment.

b) Safety devices.

c) Lifting accessories. (c)

Chains, ropes, and belts.

d) Removable mechanical transmission systems.

(2) This Regulation also covers partly completed machines.

(3) For the purposes of this Regulation, machinery, the relevant products specified in the first paragraph, and partly completed machinery are collectively referred to as "products covered by this Regulation."

(4) This Regulation does not cover the following products:

a) Safety components supplied by the manufacturer of the original machines, related products, and partly completed machines and intended for use as replacement parts to replace identical components.

b) Special equipment designed for use in fairgrounds or amusement parks.

c) Machines and related products specifically designed for use in a nuclear facility or used in a nuclear facility, where compliance with this Regulation could compromise the nuclear safety of said facility.

(c) Weapons, including firearms.

d) Vehicles used for transportation via air, water, and rail networks, excluding any machinery mounted on them.

e) Aviation products, parts, and equipment that fall within the scope of the relevant EU legislation governing common rules for civil aviation—to the extent that such legislation covers the essential health and safety requirements specified in this Regulation—and that also fall under the definition of "machinery" in this Regulation.

f) Regulation on Type Approval and Market Surveillance and Control of Motor Vehicles and Trailers, as well as Their Components, Systems, and Separate Technical Units, published in the Official Gazette No. 31104 dated April 19, 2020 (EU/2018/858), excluding machinery mounted on such vehicles, as well as motor vehicles and their trailers, and systems, components, separate technical units, parts, and equipment designed and manufactured for these vehicles.

g) The Regulation on the Type Approval and Market Surveillance and Control of Two- or Three-Wheeled Motor Vehicles and Four-Wheeled Motorcycles (EU/168/2013) excluding machinery mounted on such vehicles, two- or three-wheeled vehicles and four-wheeled motorcycles, as well as systems, assemblies, separate technical units, parts, and equipment designed and manufactured for such vehicles.

ğ) The Regulation on Type Approval and Market Surveillance and Control of Agricultural and Forestry Vehicles (EU/167/2013), published in the Official Gazette No. 29088 dated August 14, 2014 excluding machinery mounted on these tractors, agricultural and forestry tractors, as well as systems, assemblies, separate technical units, parts, and equipment designed and manufactured for these tractors.

h) Motor vehicles intended solely for use in competitions.

(i) Vessels operating at sea, mobile offshore units, and machinery mounted on such vessels or units.

i) Machines or related products specifically designed and manufactured for military or law enforcement purposes.

j) Machines or related products specifically designed and manufactured for temporary use in laboratories for research purposes.

k) Mine shaft elevators.

l) Machines or related products intended to transport performers during artistic performances.

m) Regulation on Electrical Equipment Designed for Specific Voltage Limits, published in the Official Gazette No. 29845 dated October 2, 2016 (2014/35/EU) or the Radio Equipment Regulation (2014/53/EU) published in the Official Gazette No. 31295 dated November 5, 2020;

1) Household appliances intended for indoor use, excluding electrically powered furniture.

2) Audio and video equipment.

3) Information technology equipment.

4) Standard office machines, excluding additive manufacturing machines used to produce three-dimensional products.

5) Low-voltage switchgear and control panels.

6) Electric motors.

n) The following high-voltage electrical products:

1) Switches and control panels.

2) Transformers.

Legal Basis

ARTICLE 3—(1) This Regulation has been prepared pursuant to the third paragraph of Article 4 of the Product Safety and Technical Regulations Law No. 7223 dated March 5, 2020, and Article 388 of the Presidential Decree No. 1 on the Organization of the Presidency.

Definitions and Abbreviations

ARTICLE 4—(1) The terms used in this Regulation shall have the following meanings:

a) EU: The European Union,

b) Accreditation: The official recognition by a national accreditation body that a conformity assessment body meets the requirements established by relevant national and international standards, as well as any additional requirements set forth in relevant sectoral regulations, to perform specific conformity assessment activities;

c) Ministry: The Ministry of Industry and Technology,

(c) Union harmonization legislation: EU legislation harmonizing the conditions for placing products on the market,

d) “CE” marking: The marking affixed by the manufacturer to indicate that the machine or related product complies with the relevant requirements set forth in the technical regulations requiring the affixing of the “CE” marking,

e) Distributor: Any natural or legal person in the supply chain, other than the manufacturer or importer, who makes a product covered by this Regulation available on the market,

f) Interchangeable equipment: Equipment—other than tools—that is attached to a machine, agricultural tractor, or forestry tractor by the operator after the machine, agricultural tractor, or forestry tractor has been placed on the market, with the aim of changing its function or adding a new function,

g) Safety component: A physical or digital component—including software—of a product covered by this Regulation that is designed or intended to perform a safety function, is placed on the market independently, and, in the event of failure or malfunction, endangers human safety but is not necessary for the product to perform its intended function or can be replaced by standard components,

ğ) Safety function: A function that serves to implement a protective measure designed to eliminate a risk or, if that is not possible, to reduce it, and whose failure could lead to an increase in the risk in question,

h) Recall: Any measure aimed at retrieving a product covered by this Regulation that has been made available to the user,

(i) Ropes: Ropes designed and manufactured for lifting purposes, either as part of a lifting machine or as lifting accessories,

i) Putting into service: The first use of a machine or related product in accordance with its intended purpose,

j) Economic operator: The manufacturer, authorized representative, importer, or distributor,

k) Manufacturer:

1) A natural or legal person who manufactures products covered by this Regulation, or who designs or commissions the manufacture of such products, and places them on the market under their own name or trademark,

2) A natural or legal person who manufactures products covered by this Regulation and puts them into service for their own use,

l) Importer: A natural or legal person established in Turkey who imports a product covered by this Regulation and places it on the market,

m) Lifting accessory: Parts or equipment—including slings and their components—that are not mounted on a lifting machine but enable the load to be held; these are placed between the machine and the load, on the load itself, or are intended to be an integral part of the load, and are placed on the market independently,

n) Belt: Belts designed and manufactured as part of a lifting machine or lifting accessory for lifting purposes,

o) Source code: The currently installed version of the software for a product covered by this Regulation, written in a programming language in a manner that leaves no room for doubt and is understandable to humans,

(o) Partially completed machine: An assembly that is not yet considered a machine because it cannot perform a specific application on its own, and is intended solely to be incorporated into a machine or other partially completed machine or equipment, or

to form a machine,

p) Commission: The European Commission,

r) Service life: The effective period during which the machine or related product is usable, starting from the moment it is placed on the market or put into service, and ending when it is discarded, including stages such as transportation, assembly, disassembly, decommissioning, scrapping, or other physical or digital modifications as foreseen by the manufacturer,

s) Instructions for use: Information provided by the manufacturer when the machine or related product is placed on the market or put into service to inform the user of the machine or related product about its intended and proper use; to provide information on the precautions to be taken and safety considerations while using or installing the machine or related product, as well as how to keep it safe, and to ensure it remains fit for purpose throughout its entire service life,

(ş) Machine;

1) An assembly consisting of interconnected parts or components—at least one of which is moving—equipped with or intended to be equipped with a drive system other than direct human or animal power, and assembled for a specific application,

2) an assembly referred to in subparagraph (1) that lacks the components necessary solely for connection to the area of use or to the source of energy and motion,

3) a device referred to in subparagraphs (1) and (2) that is ready for installation and can operate only when mounted on a means of transport or installed in a building or structure,

4) Machinery assemblies or partially completed machinery assemblies referred to in subparagraphs (1), (2), and (3), which are configured and controlled to operate as a whole to achieve the same result,

5) Assemblies consisting of interconnected parts or components—at least one of which is movable—connected to each other for the purpose of lifting loads, where the sole power source is direct human effort,

6) Equipment referred to in subparagraphs (1), (2), (3), (4), and (5) but on which the software intended solely for its specific application as specified by the manufacturer has not been installed.

t) Notified body: A conformity assessment body notified in accordance with this Regulation,

u) Significant modification: A modification to the machine or related product, made after it has been placed on the market or put into service, that was not foreseen or planned by the manufacturer, that affects the safety of the machine or related product by creating a new hazard or increasing an existing risk, and that is carried out using physical or digital means and requires one of the following:

1) The addition of enclosures or protective devices involving procedures that require modifying the machine's or related product's existing safety control system,

2) The implementation of additional protective measures to ensure the stability or mechanical durability of the machine or related product,

ü) Placing on the market: The supply of a product covered by this Regulation to the market for distribution or use, whether for a fee or free of charge, as part of commercial activities,

v) Withdrawal from the market: Any measure aimed at preventing a product covered by this Regulation, which is present in the supply chain, from being made available on the market,

y) Placing on the market: The first time a product covered by this Regulation is made available on the market,

z) Professional user: A natural person who uses or operates the machine or related product within the scope of their professional activity or business,

aa) Removable mechanical transmission component: Removable equipment that, when placed on the market together with its housing—which transmits power from the first fixed mounting point where it is connected between a self-propelled machine or tractor and another machine or related product—is considered a single product,

bb) Technical specifications: The document specifying the technical requirements that products covered by this Regulation must meet,

cc) Essential health and safety requirements: The mandatory provisions set forth in Annex 3 regarding the design and manufacture of products covered by this Regulation, established to ensure a high level of protection for human health and safety, and, where applicable, for domestic animals, goods, and the environment,

(cc) TÜRKAK: The Turkish Accreditation Agency,

dd) Conformity assessment body: An organization that carries out conformity assessment activities, including calibration, testing, certification, and inspection,

ee) Conformity assessment: The process demonstrating whether the essential health and safety requirements set forth in this Regulation and applicable to machinery or related products have been met,

ff) Harmonized standard: A standard adopted at the request of the Commission to enable the implementation of EU harmonization legislation,

gg) Member State: A member state of the European Union,

ğğ) Competent authority: A public authority that prepares, enforces, or supervises technical regulations concerning products,

hh) Authorized representative: A natural or legal person established in Turkey who is appointed in writing by the manufacturer to fulfill certain obligations of the manufacturer under the legislation on the manufacturer's behalf,

(ii) Chains: Chains designed and manufactured as part of a lifting machine or lifting accessories for the purpose of lifting,

means.

PART TWO
General Obligations

Free Circulation

ARTICLE 5—(1) The Ministry shall not prevent the placing on the market of products covered by this Regulation or the putting into service of machinery or related products compliant with this Regulation on grounds related to matters covered by this Regulation.

(2) Products covered by this Regulation but not in compliance with it may be displayed at trade fairs, exhibitions, promotional activities, or similar events, provided that a clearly visible label is prominently displayed stating that the product does not comply with this Regulation and may not be placed on the market until it is brought into compliance. However, necessary measures must be taken to ensure the safety of people throughout these promotional activities.

Protection of Persons During the Installation or Use of Machinery or Related Products

ARTICLE 6—(1) The Ministry may establish requirements to ensure the protection of people, including workers, during the installation or use of machinery or related products; however, these rules shall not permit the machinery or related product to be modified in a manner that would constitute a violation of this Regulation.

Categories of machinery and related products listed in Annex 1 that are subject to the relevant conformity assessment procedures

ARTICLE 7—(1) Machinery and related products falling under the categories listed in Annex 1, Part A, are subject to the specific conformity assessment procedures set forth in the second paragraph of Article 26. Machinery and related products falling under the categories listed in Annex 1, Part B, are subject to the specific conformity assessment procedures set forth in the third paragraph of Article 26.

(2) Commission regulations regarding amendments to Annex 1 shall be published by the Ministry.

(3) If the Ministry has any doubts as to whether a machine or related product category is listed in Annex 1, it shall immediately notify the Commission of this matter, along with its reasons, through the Ministry of Trade.

Safety Components

ARTICLE 8—(1) An indicative list of safety components is set forth in Annex 2.

(2) Commission regulations regarding amendments to Annex 2 shall be published by the Ministry.

(3) If the Ministry has any doubts regarding whether a safety component should be listed in Annex 2, it shall immediately notify the Commission of this matter, along with its reasons, through the Ministry of Trade.

Essential health and safety requirements for products covered by this Regulation

ARTICLE 9—(1) Machinery or related products may be placed on the market or put into service provided they are properly installed, maintained, and used in accordance with their intended purpose or under reasonably foreseeable conditions, and provided they meet the essential health and safety requirements specified in Annex 3.

(2) Partially completed machinery may be placed on the market only if it meets the relevant essential health and safety requirements specified in Annex 3.

(3) Commission regulations regarding amendments to Annex 3 in connection with the addition of health and safety requirements for artificial intelligence systems classified as high-risk shall be published by the Ministry.

Union Harmonization Legislation

ARTICLE 10—(1) For a specific product falling within the scope of this Regulation, where the risks addressed by the essential health and safety requirements set forth in Annex 3 are fully or partially covered by Union harmonization legislation that is more specific than this Regulation, this Regulation shall not apply to the product in question to the extent that such Union legislation covers those risks.

PART THREE
Obligations of Economic Operators

Obligations of Manufacturers of Machinery and Related Products

ARTICLE 11—(1) Manufacturers shall ensure that, when placing a machine or related product on the market or putting it into service, the product is designed and manufactured in accordance with the essential health and safety requirements specified in Annex 3.

(2) Manufacturers shall prepare the technical file specified in Annex 4, Part A, and apply or have applied the relevant conformity assessment procedure referred to in Article 26 before placing the machine or related product on the market or putting it into service. Where the conformity of the machine or related product with the essential health and safety requirements specified in Annex 3

, manufacturers shall draw up the EU Declaration of Conformity in accordance with Article 22 and affix the CE marking in accordance with Article 25.

(3) Manufacturers shall keep the technical file and the EU Declaration of Conformity at the disposal of the market surveillance and inspection authority for at least 10 years from the date the machine or related product is placed on the market or put into service. Where applicable, the source code or programming logic contained in the technical file shall be submitted to the Ministry upon a reasoned request, provided that it is necessary to verify compliance with the essential health and safety requirements specified in Annex 3.

(4) Manufacturers shall ensure that the necessary processes are in place to maintain the conformity of the machine or related product, which is part of serial production, with this Regulation. Changes occurring in the production process, design, or characteristics of the machine or related product, as well as changes in the harmonized standards, other technical specifications, or common characteristics referred to in Article 21 upon which the declaration of conformity of the machine or related product is based, shall be taken into due account. Manufacturers shall, where deemed appropriate in light of the risks posed by the machinery or related products, take samples from machinery or related products placed on the market and test them to protect the health and safety of users, and shall review the results. Manufacturers shall, where necessary, keep records of complaints, nonconforming machinery or related products, and recalled machinery or related products, and shall inform distributors of such monitoring activities.

(5) Manufacturers; ensure that the machinery or related products they place on the market or put into service bear, at a minimum, the model, serial, or type designation; the year of manufacture (the year the manufacturing process was completed); and, if applicable, the lot or serial number or other identifying information; or, where the size or nature of the machinery or related product does not permit this, ensure that the required information appears on the packaging or in the documentation provided with the machinery or related product.

(6) Manufacturers shall indicate their names, registered trade names, or registered trademarks, mailing addresses, and the website, email address, or other digital contact information through which they can be reached on the machine or related product; or, where this is not possible, on the packaging or in the documentation accompanying the machine or related product. The address shall indicate the single point of contact for the manufacturer. Contact information shall be provided in a language that users and market surveillance and inspection authorities can easily understand.

(7) Manufacturers shall ensure that the instructions for use of the machine or related product are provided together with the information specified in Annex 3. The instructions may be provided in digital format. Such instructions and information shall clearly indicate which product model they correspond to. When the instructions for use are provided in digital format, the manufacturer shall:

a) indicate on the machine or related product—or, if this is not possible, on the packaging or in the accompanying documentation—how to access the digital instructions.

b) Provide the instructions for use in a format that allows the user to print, download, and save them to an electronic device so that the user can access them at any time, including in the event of a malfunction of the machine or related product. This requirement also applies when the instructions for use are embedded in the software of the machine or related product.

c) The manufacturer shall ensure that the instructions for use remain accessible online throughout the expected service life of the machine or related product and for at least 10 years after the machine or related product is placed on the market.

(8) Upon the user’s request at the time of purchase, the manufacturer shall provide the instructions for use in paper format free of charge within one month. If the machine or related product is intended for non-professional users, or even if it is not intended for non-professional users but can reasonably be expected to be used by non-professional users under foreseeable conditions, the manufacturer shall provide, in paper format, the essential safety information necessary for the machine or related product to be put into service and used safely. The instructions for use, safety information, and the information specified in Annex 3 shall be in Turkish and shall be easily understandable, clear, and legible to users.

(9) Manufacturers shall ensure that the machine or related product is provided together with the EU Declaration of Conformity specified in Annex 5, Part A; or, alternatively, manufacturers shall provide the web address where the EU Declaration of Conformity can be accessed or a machine-readable code in the instructions for use and the information specified in Annex 3. Digital EU Declarations of Conformity shall remain accessible online throughout the expected service life of the machine or related product and, in any case, for at least 10 years following the placing on the market or putting into service of the machine or related product.

(10) Manufacturers who believe that the machinery or related product they have placed on the market or made available for use does not comply with this Regulation, or who have reasonable grounds to believe so, shall immediately take the corrective measures deemed appropriate to bring such machinery or related product into compliance, withdraw it from the market, or recall it. Furthermore, in cases where the machine or related product poses a risk to human health and safety, and where applicable, to pets and property, and where applicable, to the environment, manufacturers shall immediately notify the Ministry of this matter, providing detailed information, in particular regarding the nonconformity and the corrective measures taken.

(11) Manufacturers shall, upon a reasoned request from the Ministry, submit all information and documents necessary to demonstrate the conformity of the machine or related product with this Regulation, in Turkish or in a language accepted by the Ministry, in written or digital format. Upon request, manufacturers shall cooperate with the Ministry regarding any measures taken to eliminate risks posed by machinery or related products they have placed on the market or made available for use.

Obligations of Manufacturers of Partly Completed Machinery

ARTICLE 12—(1) When placing partially completed machinery on the market, manufacturers shall ensure that the product in question is designed and manufactured in accordance with the relevant essential health and safety requirements specified in Annex 3.

(2) Manufacturers shall prepare the technical file specified in Annex 4, Part B, before placing the partly completed machinery on the market. Where the conformity of the partly completed machinery with the relevant essential health and safety requirements specified in Annex 3 is demonstrated in the technical file specified in Annex 4, Part B, manufacturers shall draw up the EU Declaration of Conformity in accordance with Article 23.

(3) Manufacturers shall keep the technical file and the EU Declaration of Incorporation available to the Ministry for at least 10 years from the date the partly completed machine is placed on the market. Where applicable, the source code or programming logic contained in the technical file shall be submitted to the Ministry upon a reasoned request, provided that it is necessary to verify compliance with the relevant essential health and safety requirements specified in Annex 3.

(4) Manufacturers shall ensure that the necessary processes are in place to maintain the compliance of the partly completed machinery, which is part of serial production, with this Regulation. Changes occurring in the production process, design, or characteristics of the partially completed machine, as well as changes in the harmonized standards or other technical specifications—or the common characteristics referred to in Article 21—on which the conformity of the partially completed machine is declared or verified, shall be taken into due account.

(5) Manufacturers shall ensure that the partly completed machinery they place on the market bears, at a minimum, its identification, the year of manufacture (as the year the manufacturing process was completed), its model and series or type, and, if applicable, the lot or serial number or other information serving as identification; or, in cases where the size or nature of the partly completed machinery does not permit this, ensure that the required information is included on the packaging or in the documentation provided with the partially completed machine.

(6) Manufacturers shall indicate their names, registered trade names, or registered trademarks, mailing addresses, and the website, email address, or other digital contact information through which they can be reached on the partly completed machine or, where this is not possible, on its packaging or in the documentation accompanying the partly completed machine. The address shall indicate the single point of contact for the manufacturer. The contact information shall be provided in a language that is easily understandable by the person integrating the partly completed machine into a machine and by the market surveillance and control authority.

(7) Manufacturers shall ensure that the partially completed machine is supplied together with the assembly instructions specified in Annex 11. The assembly instructions may be provided by the manufacturer in digital format. When the assembly instructions are provided in digital format, the manufacturer shall:

a) indicate on the partially completed machine—or, if this is not possible, on its packaging or in the accompanying documentation—how to access the digital assembly instructions.

b) Provide the assembly instructions in a format that allows the person integrating the partially completed machine into the machine to print, download, and save them to an electronic device so that they are accessible at all times, including in the event of a malfunction of the partially completed machine. This requirement also applies when the assembly instructions are embedded in the software of the partially completed machine.

c) The manufacturer ensures that the assembly instructions remain accessible online for at least 10 years after the partially completed machine is placed on the market.

(8) Upon request by the person integrating the partly completed machine into a machine at the time of purchase, the manufacturer shall provide the assembly instructions in paper format free of charge within one month. The assembly instructions shall be in Turkish and shall be clear, legible, and easily understandable by the person integrating the partly completed machine into a machine.

(9) Manufacturers shall ensure that the partially completed machine is supplied together with the EU Declaration of Incorporation specified in Annex 5, Part B; or, alternatively, manufacturers shall provide, in the assembly instructions specified in Annex 11, the web address where the EU Declaration of Incorporation can be accessed or a machine-readable code. Digital EU declarations of incorporation shall remain accessible online for at least 10 years after the partially completed machine is placed on the market.

(10) Manufacturers who believe that the partly completed machinery they have placed on the market does not comply with this Regulation, or who have reasons to believe so, shall immediately take the corrective measures deemed appropriate to bring the partly completed machinery into compliance, withdraw it from the market, or recall it. Furthermore, if the partly completed machine poses a risk with regard to the relevant essential health and safety requirements, manufacturers shall immediately notify the Ministry of this matter, providing detailed information, in particular regarding the nonconformity and the corrective measures taken.

(11) Upon a reasoned request from the Ministry, manufacturers shall submit all information and documents necessary to demonstrate the partially completed machine’s compliance with this Regulation, in Turkish or in a language acceptable to the Ministry, in written or digital format. Upon request, manufacturers shall cooperate with the Ministry regarding any measures taken to eliminate the risks associated with the partially completed machines they have placed on the market, in relation to the relevant essential health and safety requirements.

Authorized Representative

ARTICLE 13—(1) The manufacturer of a product covered by this Regulation may appoint an authorized representative by written authorization. The obligations set forth in the first paragraph of Article 11 and the first paragraph of Article 12, as well as the obligation to prepare the technical file specified in Annex 4,

shall not fall within the authorized representative's scope of authority.

(2) The authorized representative shall perform the specified tasks within the scope of the authority granted by the manufacturer. These authorities permit the authorized representative to perform at least the following:

a) Ensuring that the technical file for the machine or related products and the EU Declaration of Conformity, or the EU Declaration of Incorporation for a partially completed machine, are kept available to the market surveillance and inspection authority for a period of at least 10 years from the date the product is placed on the market.

b) Upon a reasoned request from the Ministry, submitting all necessary information and documents in paper or digital format to the Ministry to demonstrate the conformity of the product covered by this Regulation.

c) Upon request, cooperate with the Ministry regarding any measures taken to eliminate the risks posed by products covered by this Regulation, including within the scope of its mandate.

Obligations of Importers of Machinery or Related Products

ARTICLE 14—(1) Importers shall place only compliant machinery or related products on the market.

(2) Importers shall ensure that, prior to placing the machine or related product on the market, the manufacturer has carried out the appropriate conformity assessment procedure referred to in Article 26. Importers shall ensure that the manufacturer has prepared the technical file specified in Annex 4, Part A; that the machinery or related product bears the CE marking referred to in Article 24; that the necessary documents accompany the product; and that the manufacturer complies with the requirements set forth in the fifth, sixth, and ninth paragraphs of Article 11. If an importer believes that the machine or related product does not comply with the requirements of this Regulation, or has grounds to believe it does not comply, the importer may not place the product on the market until it is brought into compliance with this Regulation. Furthermore, if the machine or related product poses a risk to human health and safety, and where applicable, to pets and property, as well as to the environment where applicable, the importer shall notify the manufacturer and the Ministry of this matter.

(3) Importers shall indicate their names, registered trade names or registered trademarks, mailing addresses, and the website, email address, or other digital contact information through which they can be reached on the machine or related product, or, where this is not possible, on the packaging or in the documentation accompanying the machine or related product. The contact information shall be provided in a language that is easily understandable by end users and the market surveillance and control authority.

(4) Importers shall ensure that the machine or related product is accompanied by instructions for use and the information specified in the seventh and eighth paragraphs of Article 11.

(5) Importers shall ensure that, while the machine or related product is under their responsibility, storage or transport conditions do not compromise compliance with the essential health and safety requirements set forth in Annex 3.

(6) Importers shall, when deemed necessary in relation to the risk posed by the machine or related product, take samples from machines or related products placed on the market and test them to ensure the protection of human health and safety, and, where appropriate, the protection of pets and property, and, where applicable, the protection of the environment; and, if deemed necessary, maintain records of complaints, non-compliant machinery or related products, and recalled machinery or related products, and inform distributors about these monitoring activities.

(7) If importers believe that a machine or related product placed on the market does not comply with this Regulation, or if they have grounds to believe it does not comply, they shall immediately take the corrective measures deemed appropriate—such as bringing the machine or related product into compliance, withdrawing it from the market, or recalling it. Furthermore, if a machine or related product poses a risk to human health and safety, and where applicable, to pets and property, as well as to the environment, the importer shall immediately notify the Ministry of this matter, providing details regarding the nonconformity and all corrective measures taken.

(8) Importers shall retain a copy of the EU Declaration of Conformity for at least 10 years from the date the machine or related product is placed on the market and, upon the Ministry's request, submit the technical file to the Ministry as specified in Annex 4, Part A. Where applicable, importers shall, upon a reasoned request from the Ministry, submit the source code or programming logic contained in the technical file to the Ministry so that the Ministry may verify compliance with the essential health and safety requirements set forth in Annex 3.

(9) Importers shall, in accordance with a reasoned request from the Ministry, submit all information and documents demonstrating the conformity of the machine or related product to this Regulation in paper or digital format, in Turkish or in a language acceptable to the Ministry. Importers shall cooperate with the Ministry, upon the Ministry's request, regarding any measures taken to eliminate risks posed by the machinery or related product they place on the market to human health and safety, and, where applicable, to pets and property, as well as to the environment.

Obligations of Importers of Partly Completed Machinery

ARTICLE 15—(1) Importers shall place only compliant partially completed machinery on the market.

(2) Before placing a partially completed machine on the market, importers shall ensure that the manufacturer has prepared the technical file specified in Annex 4, Part B; that the partially completed machine is accompanied by the necessary documentation; and that the manufacturer complies with the requirements set forth in the fifth, sixth, and ninth paragraphs of Article 12. If an importer believes that a partly completed machine does not comply with the requirements of this Regulation, or has grounds to believe it does not comply, the importer may not place this

product until it is brought into compliance with this Regulation. Furthermore, if the partly completed machine poses a risk with respect to the relevant essential health and safety requirements, the importer shall inform the manufacturer and the Ministry of this matter.

(3) Importers shall indicate their name, registered trade name, or registered trademark, as well as a mailing address and website, email address, or other digital contact information on the partly completed machine or, where this is not possible, on the packaging or in the documentation accompanying the product. The contact information shall be provided in a language that is easily understandable to the person integrating the partly completed machine into the machine and to the market surveillance and control authority.

(4) Importers shall ensure that the partly completed machine is supplied together with the assembly instructions specified in the seventh and eighth paragraphs of Article 12.

(5) Importers shall ensure that, while the partly completed machine is under their responsibility, storage or transport conditions do not compromise compliance with the relevant essential health and safety requirements set forth in Annex 3.

(6) If importers believe that a partially completed machine placed on the market does not comply with this Regulation, or if they have reasonable grounds to believe it does not comply, they shall immediately take the corrective measures deemed appropriate—such as bringing the partially completed machine into compliance, withdrawing it from the market, or recalling it. Furthermore, if the partially completed machine poses a risk with regard to the relevant essential health and safety requirements, the importer shall immediately notify the Ministry of this matter, providing details regarding the nonconformity and all corrective measures taken.

(7) Importers shall retain a copy of the EU Declaration of Conformity for at least 10 years from the date the partially completed machine is placed on the market and shall submit the technical file specified in Annex 4, Part B, to the Ministry upon its request.

(8) Importers shall, upon a reasoned request from the Ministry, submit all information and documents demonstrating the partially completed machine's compliance with this Regulation in paper or digital format, in Turkish or in a language acceptable to the Ministry. Importers shall cooperate with the Ministry, upon request, regarding any measures taken to eliminate the risks posed by the partially completed machinery they have placed on the market in relation to the relevant essential health and safety requirements.

Obligations of Distributors of Machinery or Related Products

ARTICLE 16—(1) Distributors shall act with due care in accordance with the requirements of this Regulation while making the machine or related product available on the market.

(2) Before making a machine or related product available on the market, the distributor shall:

a) Verify that the machine or related product bears the CE marking,

b) that the machine or related product is accompanied by the EU Declaration of Conformity specified in the ninth paragraph of Article 11

,

c) that the machine or related product is accompanied by the instructions for use and

information specified in the seventh and eighth paragraphs of Article 11 are included and are in Turkish,

(c) The manufacturer and importer comply with the requirements specified in the fifth and sixth paragraphs of Article 11 and the third paragraph of Article 14, respectively,

confirm.

(3) If the distributor believes that the machine or related product does not comply with this Regulation, or has grounds to believe it does not comply, the distributor may not keep such machine or related product on the market until it is brought into compliance. Furthermore, if the machine or related product poses a risk to human health and safety, and where applicable, to pets and property, as well as to the environment where applicable, the distributor shall notify the manufacturer or importer and the Ministry accordingly.

(4) The distributor shall ensure that, while the machine or related product is under its responsibility, storage or transport conditions do not compromise compliance with the essential health and safety requirements specified in Annex 3.

(5) If the distributor believes that a machine or related product it has placed on the market does not comply with this Regulation, or if there are grounds to believe it does not comply, the distributor shall ensure that appropriate corrective measures—such as bringing the machine or related product into compliance, withdrawing it from the market, or recalling it—are taken. Furthermore, if the machinery or related product poses a risk to human health and safety, and where applicable, to pets and property, as well as to the environment, the distributor shall immediately notify the Ministry of this matter, providing details regarding the nonconformity and all corrective measures taken.

(6) Upon a reasoned request from the Ministry, the distributor shall submit all information and documents demonstrating the conformity of the machine or related product with this Regulation in paper or digital format, in Turkish or in a language accepted by the Ministry. Upon request, the distributor shall cooperate with the Ministry regarding any measures taken to eliminate risks posed by the machinery or related product it places on the market to human health and safety, and, where applicable, to pets, property, and the environment.

Obligations of Distributors of Partly Completed Machinery

ARTICLE 17—(1) Distributors shall act with due care in accordance with the requirements of this Regulation while making partially completed machinery available on the market.

(2) Before placing a partly completed machine on the market, the distributor shall:

a) Ensure that the partially completed machine is accompanied by the EU Declaration of Incorporation specified in the ninth paragraph of Article 12;

b) Ensure that the partially completed machine is accompanied by the assembly instructions specified in the seventh and eighth paragraphs of Article 12 and that these instructions are in Turkish;

c) The manufacturer and importer comply with the requirements specified in the fifth and sixth paragraphs of Article 12 and the third paragraph of Article 15, respectively,

confirms.

(3) If the distributor believes that the partly completed machine does not comply with this Regulation, or has grounds to believe that it does not comply, the distributor may not keep the partly completed machine on the market until it is brought into compliance. Furthermore, if the partly completed machine poses a risk with regard to the relevant essential health and safety requirements, the distributor shall inform the manufacturer or importer, as well as the Ministry, accordingly.

(4) The distributor shall ensure that, while the partly completed machine is under its responsibility, storage or transport conditions do not compromise compliance with the relevant essential health and safety requirements specified in Annex 3.

(5) If the distributor believes that a partially completed machine it has placed on the market does not comply with this Regulation, or if there are grounds to believe it does not comply, the distributor shall ensure that appropriate corrective measures—such as bringing the partially completed machine into compliance, withdrawing it from the market, or recalling it—are taken. Furthermore, in cases where the partly completed machine poses a risk with regard to the relevant essential health and safety requirements, the distributor shall immediately notify the Ministry of this matter, providing details regarding the nonconformity and all corrective measures taken.

(6) Upon a reasoned request from the Ministry, the distributor shall provide all information and documentation demonstrating the partially completed machine's compliance with this Regulation, in paper or digital format, in Turkish or in a language accepted by the Ministry. Upon request, the distributor shall cooperate with the Ministry regarding any measures taken to eliminate risks posed by the partially completed machine it places on the market with respect to essential health and safety requirements.

Circumstances in Which Manufacturers' Obligations Apply to Importers and Distributors

ARTICLE 18— (1) If an importer or distributor places a product covered by this Regulation on the market under its own name or trademark, or modifies a product already placed on the market in a way that could affect its compliance with applicable requirements, it shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the manufacturer's obligations set forth in Articles 11 and 12.

Other Situations in Which Manufacturer Obligations Apply

ARTICLE 19—(1) Any natural or legal person who makes a significant modification to a machine or related product shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the manufacturer's obligations set forth in Article 11 with respect to the machine or related product in question. If the significant modification affects only the safety of the machine or related product—as it is a part of the machine's assembly—these obligations apply only to the affected machine or related product, as indicated in the risk assessment.

(2) The person carrying out the significant modification shall, in particular, ensure and declare—at their own sole responsibility—that the machine or related product complies with the applicable requirements of this Regulation, without prejudice to the other obligations specified in Article 11, and shall apply the relevant conformity assessment procedures as specified in the second, third, and fourth paragraphs of Article 26.

(3) A non-professional user who makes a significant modification to their own machine or related product for their own use is not considered a manufacturer for the purposes of this Regulation and is not subject to the manufacturer's obligations specified in Article 11.

Definition of Economic Operators

ARTICLE 20—(1) Upon request by the Ministry, an economic operator shall provide the Ministry with the necessary information regarding the following matters:

a) Information regarding economic operators who supply the product to them under this Regulation.

b) Information regarding economic operators from whom they procure products covered by this Regulation.

(2) Economic operators shall retain the information specified in the first paragraph for at least 10 years from the date they supplied products covered by this Regulation or from the date such products were supplied to them, in order to fulfill the obligation set forth in the first paragraph.

SECTION FOUR

Conformity of Products Covered by This Regulation

Presumption of Conformity for Products Covered by This Regulation

ARTICLE 21—(1) A product covered by this Regulation that complies with harmonized standards or their relevant sections, the reference numbers of which have been published in the Official Journal of the European Union, is presumed to comply with the essential health and safety requirements specified in Annex 3 within the scope of those standards or relevant sections.

(2) Implementing regulations issued by the Commission regarding the establishment of common specifications covering the technical requirements for compliance with the essential health and safety requirements specified in Annex 3 are published by the Ministry

.

(3) A product covered by this Regulation that complies with the common specifications set forth in the implementing legislation referred to in the second paragraph—or in sections thereof—is presumed to comply with the essential health and safety requirements specified in Annex 3 regarding those common specifications or sections thereof.

(4) If the Ministry assesses that a common feature does not fully meet the essential health and safety requirements specified in Annex 3, it may inform the Commission through the Ministry of Trade by providing a detailed explanation.

(5) Machines and related products that have been certified or for which a declaration of conformity has been issued under a cybersecurity certification program accepted in accordance with relevant EU legislation on information and communication technology cybersecurity certification, and whose references have been published in the Official Journal of the European Union, to the extent that the relevant requirements fall within the scope of a cybersecurity certificate or declaration of conformity—or parts thereof—are presumed to comply with the essential health and safety requirements set forth in Articles 1.1.9 and 1.2.1 of Annex 3 regarding protection against tampering and the security and reliability of control systems.

(6) Until harmonized standards or common specifications relating to high-risk artificial intelligence systems are referenced or adopted pursuant to this Article, high-risk AI systems covered by this Regulation that comply with the relevant harmonized standards or accepted common specifications referenced under the EU's AI legislation shall be presumed to comply with the essential health and safety requirements set out in Annex 3 regarding high-risk AI systems.

EU Declaration of Conformity for Machinery and Related Products

ARTICLE 22—(1) The EU Declaration of Conformity demonstrates compliance with the applicable essential health and safety requirements specified in Annex 3.

(2) The EU Declaration of Conformity shall be drawn up in the format set out in Annex 5, Part A; it shall include the elements specified in the relevant modules set out in Annexes 6, 8, 9, and 10, and shall be kept up to date. Where it is drawn up in other languages, a Turkish translation of the EU Declaration of Conformity for the machine or related product shall also be included.

(3) If the machine or related product is subject to more than one technical regulation requiring an EU Declaration of Conformity, a single EU Declaration of Conformity is prepared covering all such technical regulations. The text of the declaration includes the names, publication dates, and reference numbers of the relevant technical regulations.

(4) By issuing the EU Declaration of Conformity, the manufacturer assumes responsibility for the conformity of the machine or related product with the requirements of this Regulation.

EU Declaration of Incorporation for Partly Completed Machinery

ARTICLE 23—(1) The EU Declaration of Incorporation demonstrates compliance with the relevant essential health and safety requirements specified in Annex 3.

(2) The EU Declaration of Incorporation is drawn up in the format set out in Annex 5, Part B, and is continuously updated. If it is drawn up in other languages, a Turkish translation of the EU Declaration of Incorporation for the partly completed machine is also attached.

(3) If the partly completed machine is subject to more than one technical regulation requiring an EU Declaration of Conformity, a single EU Declaration of Incorporation shall be prepared covering all such technical regulations. Said declaration shall also include the name, publication date, and reference number of the relevant technical regulations.

(4) By issuing the EU Declaration of Incorporation, the manufacturer assumes responsibility for the compliance of the partly completed machine with the requirements of this Regulation.

General Principles of the "CE" Marking

ARTICLE 24—(1) The "CE" marking shall be affixed in accordance with the "CE" Marking Regulation, which entered into force by Presidential Decree No. 4021 dated May 26, 2021.

Rules Regarding the Affixing of the "CE" Mark to Machinery and Related Products

ARTICLE 25—(1) The "CE" marking shall be affixed to the machine or related product in a visible, legible, and indelible manner. If this is not possible or cannot be guaranteed due to the structure of the machine or related product, the "CE" marking shall be affixed to the packaging and to the documents accompanying the machine or related product.

(2) The "CE" marking shall be affixed prior to the placing on the market or putting into service of the machine or related product.

(3) If the conformity of the machine or related product is assessed in accordance with the conformity assessment procedures specified in subparagraphs (a), (b), and (c) of the second paragraph and subparagraphs (b), (c), and (ç) of the third paragraph of Article 26, the identification number of the relevant notified body must be affixed following the "CE" marking. The notified body's identification number is affixed by the body itself or, at its instruction, by the manufacturer or the manufacturer's authorized representative.

(4) In addition to the "CE" marking and, where applicable, the notified body's identification number, any visual symbol or marking indicating a specific risk or use may be added.

(5) The Ministry bases its actions on current practices to ensure the proper application of the legislation governing the "CE" marking and takes the necessary measures in the event of improper use of said marking.

CHAPTER FIVE
Conformity Assessment

Conformity assessment methods and emergency procedures for machinery and related products

ARTICLE 26—(1) The manufacturer or the natural or legal person specified in Article 19 shall apply one of the conformity assessment methods specified in the second, third, and fourth paragraphs of this Article.

(2) For the category of machinery or related products listed in Annex 1, Part A, the manufacturer or the natural or legal person specified in Article 19 shall apply one of the following methods:

a) The EU type examination (Module B) specified in Annex 7, followed by conformity to type based on internal production control (Module C) as specified in Annex 8.

b) Conformity based on full quality assurance (Module H) as specified in Annex 9.

c) Conformity based on unit verification as specified in Annex 10 (Module G).

(3) For the machine or relevant product category listed in Annex 1, Part B, the manufacturer or the natural or legal person referred to in Article 19 shall apply one of the following methods:

a) Internal production control as specified in Annex 6 (Module A).

b) EU type examination as specified in Annex 7 (Module B), followed by conformity to type based on internal production control as specified in Annex 8 (Module C).

c) Conformity based on full quality assurance as specified in Annex 9

(Module H). (c) Conformity based on unit verification as specified in Annex

10 (Module G).

d) If the manufacturer applies the internal production control method specified in subparagraph (a) of this paragraph, the manufacturer shall design and manufacture the machine or related product in accordance with harmonized standards or common specifications that cover all the relevant essential health and safety requirements and are specific to that category of machine or related product. If the machine or related product category is listed in Annex 1, Part B, and the machine or related product has not been designed and manufactured in accordance with harmonized standards or common specifications that cover all the relevant essential health and safety requirements for that machine or related product category and are specific to that category, the manufacturer shall apply one of the methods specified in subparagraphs (b), (c), or (d) of this paragraph, including the natural or legal persons referred to in Article 19. shall apply one of the methods specified in subparagraphs (b), (c), or (ç) of this paragraph.

(4) If the machine or related product category is not listed in Annex 1, the manufacturer—including the natural or legal persons specified in Article 19—shall apply the internal production control procedure (Module A) specified in Annex 6.

(5) Notified bodies shall take into account the specific interests and needs of small and medium-sized enterprises when setting fees for conformity assessment.

(6) With regard to machinery and related products covered by this Regulation, should the Commission issue a regulation concerning emergency procedures for conformity assessment due to an internal market emergency, the presumption of conformity, and the acceptance of common characteristics in accordance with the EU's internal market emergency and resilience legislation, the Ministry may, where necessary, publish such a regulation or directly adopt and implement the relevant EU practices in this context.

SECTION SIX

Designation of Conformity Assessment Bodies

Notification

ARTICLE 27—(1) The Ministry shall notify the Commission, through the Ministry of Trade, of the bodies it has designated to carry out third-party conformity assessment procedures in accordance with this Regulation.

Authorized Body

ARTICLE 28—(1) The Ministry is the competent authority responsible for establishing and implementing the necessary procedures for the evaluation and designation of a candidate conformity assessment body—including the provisions set forth in Article 33—as well as for the monitoring of the designated body.

Provisions Concerning the Competent Authority

ARTICLE 29—(1) The authorized body shall conduct its activities in such a way as to avoid any conflict of interest with conformity assessment bodies.

(2) The competent authority shall conduct its activities objectively and impartially.

(3) The Competent Authority ensures that all decisions regarding conformity assessment bodies to be designated as approved bodies are made by qualified personnel and that such personnel are distinct from those who have conducted the competence assessment of the approved body.

(4) The competent authority may not offer or provide any of the activities carried out by conformity assessment bodies; nor may it offer or provide commercial or competition-based consulting services.

(5) The competent authority ensures the confidentiality of the information it obtains.

(6) The authorized body employs a sufficient number of qualified personnel to ensure that its duties are properly fulfilled.

The Ministry's Obligation to Provide Information

ARTICLE 30—(1) The Ministry shall notify the Commission, through the Ministry of Trade, of the methods used to assess the competence of candidate conformity assessment bodies for designation as approved bodies, to designate such bodies as approved bodies, to report on them, and to monitor them, as well as any changes to these methods.

Requirements for Approved Bodies

ARTICLE 31—(1) In order for a conformity assessment body to be designated as an approved body and for such designation to remain in effect, it must meet all the requirements specified in this Article.

(2) The conformity assessment body shall be established in accordance with national legislation and shall have legal personality.

(3) The conformity assessment body must be an independent third-party organization, separate from the business it assesses or the machinery or related product it evaluates. If a conformity assessment body is affiliated with a professional or trade association representing businesses involved in the design, manufacture, supply, installation, use, or maintenance of the machinery or related product it assesses, it may be considered a conformity assessment body provided it demonstrates its independence and the absence of any conflict of interest.

(4) The conformity assessment body must comply with the following requirements:

a) A conformity assessment body may not have top management or personnel responsible for carrying out conformity assessment tasks who are the designer, manufacturer, supplier, importer, distributor, installer, purchaser, owner, user, or maintainer of the machine or related product being assessed, or a representative of any of these parties. With regard to partially completed machines incorporated into the product under assessment, the body may not perform any of these roles or act as a representative of any of these parties. This restriction does not apply to the use of the machine or related product under assessment that is necessary for the activities of the conformity assessment body, nor does it apply to the use of the machine or related product for personal purposes.

b) The conformity assessment body, its top management, and the personnel responsible for performing conformity assessment tasks may not be directly involved in the design, manufacture, import, distribution, marketing, installation, use, or maintenance of machinery or related products, nor may they represent persons engaged in these activities. They may not engage in any activity that could adversely affect the independence or integrity of the decisions they make regarding the conformity assessment activities for which they are notified. These provisions apply in particular to consulting services.

c) The conformity assessment body shall ensure that the activities of its branches, representative offices, and contractors do not affect the confidentiality, objectivity, or impartiality of conformity assessment activities.

(5) The conformity assessment body and its personnel shall conduct conformity assessment activities with the highest level of professional integrity and the necessary technical competence in the relevant field; they shall refrain from any pressure—particularly from individuals or groups with a vested interest in the outcomes of these activities—and from all incentives, especially financial ones, that could influence their decisions or the results of conformity assessment activities.

(6) The conformity assessment body shall possess the competence to carry out all conformity assessment activities assigned to it within the scope specified in Annexes 7, 9, and 10, whether performed by the body itself or on its behalf or under its responsibility. For every machine or related product and every conformity assessment procedure for which it is designated, the conformity assessment body shall at all times:

a) Personnel with the technical knowledge and sufficient and appropriate experience to carry out conformity assessment activities

personnel,

b) descriptions of the methods used to conduct conformity assessment activities, ensuring the transparency and reproducibility of such methods,

c) Appropriate policies and procedures to ensure a clear distinction between the tasks it performs as a notified body and its other activities,

c) Methods regarding the performance of conformity assessment activities that take into account the size of the organization, the sector in which it operates, its organizational structure, the degree of technological complexity of the machinery or related product, and the volume and mass-production nature of the production process,

.

(7) The conformity assessment body is obligated to have the necessary tools to properly perform the technical and administrative tasks related to conformity assessment activities and to have access to all necessary equipment or facilities.

(8) Personnel responsible for conducting the conformity assessment process must:

a) have sound technical and professional training covering all conformity assessment activities for which the conformity assessment body has been designated as an accredited body,

b) Sufficient knowledge of the requirements of the assessments they conduct and the necessary authority to carry out those assessments,

c) Sufficient knowledge and understanding of the essential health and safety requirements set forth in Annex 3, the applicable harmonized standards and common specifications referred to in Article 21, and the relevant provisions of Union harmonization legislation and national legislation;

(c) The ability to prepare documents, records, and reports demonstrating that conformity assessment activities have been carried out,

must be possessed.

(9) The conformity assessment body is responsible for ensuring the impartiality of itself, its top management, and the personnel responsible for carrying out conformity assessment tasks. The

body’s senior management and the personnel carrying out conformity assessment tasks may not have their compensation tied to the number of conformity assessments performed or their results.

(10) The conformity assessment body must obtain financial liability insurance unless responsibility is assumed by the government in accordance with national legislation and the Ministry has no direct responsibility for the conformity assessment process.

(11) The personnel of the conformity assessment body shall ensure the professional confidentiality of all information obtained while performing their duties under Annexes 7, 9, and 10, except for matters related to their relationship with the Ministry. Rights pertaining to property, intellectual property, and trade secrets shall be protected.

(12) The conformity assessment body shall participate in relevant standardization activities and in the activities of the coordination group of notified bodies established by the Commission pursuant to Article 42, or shall ensure that its personnel performing conformity assessment tasks are informed of these activities. The conformity assessment body shall apply the administrative decisions and documents resulting from the work of the coordination group of notified bodies as general guidelines.

Presumption of Conformity of Notified Bodies

ARTICLE 32—(1) Where a conformity assessment body demonstrates compliance with the criteria set forth in the relevant harmonized standards or parts thereof, the references to which have been published in the Official Journal of the European Union, it shall be presumed to meet the requirements set forth in Article 31 to the extent that the applicable harmonized standards cover such requirements.

Branches, Representative Offices, and Contractors of Notified Bodies

ARTICLE 33—(1) Where a notified body assigns specific tasks related to the conformity assessment process to a subcontractor or uses its branch or representative office for such tasks, it shall ensure that these entities meet the requirements set forth in Article 31 and shall notify the Ministry of this situation.

(2) Notified bodies assume full responsibility for all activities carried out by their branches, representative offices, and contractors, regardless of where they are established.

(3) Activities may be carried out by a contractor, branch, or representative office only if an agreement is reached with the client.

(4) The accredited body shall retain the documents related to the assessment of the qualifications of the contractor, branch, or representative office, as well as the documents regarding the tasks performed by the aforementioned parties under Annexes 7, 9, and 10, to be submitted to the Ministry when required.

Notification Application

ARTICLE 34—(1) A conformity assessment body established in Turkey shall submit an application to the Ministry to be designated as a notified body.

(2) An application for designation as an approved body must include a description of the conformity assessment activities, the conformity assessment methods specified in Annexes 7, 9, and 10, and the types or categories of machinery or related products for which the conformity assessment body claims competence, as well as, if available, documentation confirming that the conformity assessment in question meets the requirements set forth in Article 31 and is in accordance with the Regulation on Conformity Assessment Bodies and Approved Bodies, which was enacted by Presidential Decree No. 4022 dated May 26,2021 and No. 4022, which entered into force pursuant to Presidential Decree No. 4022 dated May 26, 2021.

(3) Conformity assessment bodies that do not hold an accreditation certificate under the second paragraph shall, in their applications to become approved bodies, submit to the competent authority evidence and documents confirming and certifying that they possess the qualifications required of approved bodies as set forth in Article 31, as well as evidence and documents of a nature that will enable the regular monitoring of their compliance with these qualifications.

Notification Process

ARTICLE 35—(1) The Ministry shall designate only those conformity assessment bodies that meet the requirements set forth in Article 31.

(2) The Ministry notifies the Commission and member states, through the Ministry of Trade, of the bodies deemed suitable for designation. The notification is made using the electronic notification tool developed and managed by the Commission.

(3) The notification referred to in the second paragraph shall include all details of the conformity assessment activities to be carried out, the types or categories of machinery or related products covered by the conformity assessment module or modules, and information verifying the body’s competence regarding the conformity assessment method.

(4) If the Ministry designates a conformity assessment body that has not been accredited under the second paragraph of Article 34 as an approved body, it shall forward to the Ministry of Trade—for submission to the Commission—the evidence and documents verifying the body’s competence, along with arrangements ensuring the body’s regular monitoring and continued compliance with the requirements specified in Article 31.

(5) If the accreditation certificate specified in the second paragraph of Article 34 was used in the assessment of the candidate approved body’s competence, the approved body may carry out its activities as an approved body provided that no objection is raised by the Commission or other member

countries, the relevant conformity assessment body may carry out the activities of an approved body. Only a body notified in this manner shall be considered an approved body for the purposes of this Regulation.

(6) The Ministry shall notify the Commission and the member states, through the Ministry of Trade, of any relevant subsequent changes to the notification specified in the second paragraph.

Notified Body Identification Number

ARTICLE 36—(1) A conformity assessment body notified by the Ministry of Trade acquires the status of an approved body upon the Commission's assignment of an identification registration number and its publication in the European Union's NANDO System.

(2) Even if a notified body is designated under more than one piece of legislation, it shall conduct its activities using the single identification number assigned by the Commission.

Changes to the Notification

ARTICLE 37— (1) If the Ministry determines that an approved body does not meet the requirements set forth in Article 31 or has failed to fulfill the obligations specified in Article 39, or if it is informed of such a situation, the Ministry shall, depending on the severity of the non-compliance or failure to fulfill these obligations, restrict, suspend, or withdraw the notification of the approved body's activities as appropriate. The Ministry shall promptly notify the Commission of this situation through the Ministry of Trade.

(2) In the event of a restriction or suspension of activities, or the withdrawal of the notification, or if the approved body terminates its own activities, the Ministry shall ensure that the files of the approved body in question are processed by another approved body or kept ready to be submitted to the Ministry upon request.

Objections Regarding the Competence of Approved Organizations

ARTICLE 38—(1) The Ministry shall forward to the Ministry of Trade, for submission to the Commission upon request, all information serving as the basis for the designation of an approved body or regarding the continued competence of such an approved body.

(2) Should the Commission or a member state of the European Union request an examination of the technical competence and compliance with relevant legislation of a notified body designated by the Ministry, the Ministry shall follow the procedure set forth in Article 4 of Decision No. 1/2006 of the Turkey-European Union Association Council. The Ministry shall forward the necessary information and documents to the Ministry of Trade, establish the necessary cooperation with the relevant parties, and take the necessary measures.

Obligations of Notified Bodies

ARTICLE 39—(1) The notified body shall conduct the conformity assessment in accordance with the conformity assessment methods specified in Annexes 7, 9, and 10.

(2) The notified body shall carry out its activities in a proportionate manner, avoiding unnecessary burdens on economic operators and taking into account the size of the business, the sector in which it operates, its structure, the degree of complexity of the technology in question, and whether the production process is mass or serial in nature. In doing so, the Notified Body takes into account the degree of diligence and the level of protection required to ensure that the machine or related product complies with the requirements of this Regulation.

(3) If the notified body determines that the manufacturer has not complied with the essential health and safety requirements specified in Annex 3 or the relevant harmonized standards or common specifications referred to in Article 21, it shall require the manufacturer to take appropriate corrective measures and shall not issue an EU type-examination certificate, grant a quality system approval decision, or issue a unit verification certificate.

(4) If, during the conformity monitoring process following the issuance of a conformity assessment decision in accordance with Annex 9, the notified body determines that the machine or related product no longer meets the relevant requirements, it shall require the manufacturer to take the necessary corrective actions and, where necessary, suspend or withdraw the conformity assessment decision. If the notified body determines that corrective actions have not been taken or that the actions taken have not had the desired effect, it shall restrict, suspend, or withdraw the approval decision as appropriate.

Appeals Against Decisions of Notified Bodies

ARTICLE 40—(1) The notified body shall ensure that a transparent and accessible appeal procedure is in place

.

Information Obligations of Notified Bodies

ARTICLE 41—(1) The notified body shall inform the Ministry regarding the following matters:

a) the rejection,

restriction, suspension, or withdrawal of the EU type-examination certificate, the quality system approval decision, or the unit verification certificate;

b) Any circumstance affecting the scope or conditions of the notification.

c) Any request for information received from the market surveillance and inspection body regarding the conformity assessment activities it conducts.

(c) Upon request, conformity assessment activities carried out within the scope of the notification, cross-border activities, and other activities, including those of subcontractors.

(2) The notified body shall provide other notified bodies that have been notified under this Regulation and that conduct similar conformity assessment activities covering the same type of machinery or related products with the necessary information regarding negative conformity assessment results and, upon request, positive conformity assessment results.

Coordination of Notified Bodies

ARTICLE 42—(1) Notified bodies shall participate, either directly or through their representatives, in the work of the sectoral group of notified bodies established by the Commission under this Regulation. The Ministry shall ensure the necessary coordination for the participation of notified bodies in the working group, if required.

SECTION SEVEN

Market Surveillance, Inspection, and Protective Measures

National-level actions regarding products posing a risk under this Regulation

ARTICLE 43—(1) If the Ministry finds sufficient grounds to believe that a product covered by these Regulations poses a risk to human health and safety, and, where applicable, to pets and property, and, where applicable, to the environment, it shall subject the product in question to an assessment that covers all relevant requirements set forth in these Regulations. The relevant economic operators shall cooperate with the Ministry as necessary for this purpose.

(2) If, as a result of the assessment referred to in the first paragraph, the Ministry determines that a product covered by this Regulation does not comply with the requirements set forth herein, it shall take measures to remedy the noncompliance or eliminate the hazard; or, where this is not possible, to mitigate the risk identified by the Ministry, the Ministry shall, without delay, request that the relevant economic operator take the appropriate and proportionate corrective measures specified in the third paragraph of Article 20 of the Framework Regulation on Market Surveillance and Control of Products, enacted by Presidential Decree No. 4269 dated July 9, 2021, within a reasonable timeframe commensurate with the nature of the risk referred to in the first paragraph, from the relevant economic operator without delay.

(3) The Ministry shall inform the relevant accredited body regarding the matter.

(4) If the Ministry determines that the nonconformity is not limited to the country's borders, it shall inform the Commission and the member states, through the Ministry of Trade, of the results of its assessment and the measures it has requested the economic operator to take.

(5) The economic operator shall ensure that all appropriate corrective measures are taken regarding all products it places on the market under this Regulation.

(6) If the relevant economic operator fails to take the corrective measures specified in the second paragraph within the specified timeframe, or if the nonconformity specified in the second paragraph or the risk specified in the first paragraph persists, the Ministry shall ensure that the products are prohibited from being placed on the market, restricted, withdrawn from the market, or recalled. The Ministry shall promptly notify the public and the Commission, through the Ministry of Trade, of these measures.

(7) The notification referred to in the sixth paragraph shall include all available details, particularly the data necessary to identify the non-compliant product covered by this Regulation, the origin of the product in question, the nature of the alleged non-compliance and the associated risk, the nature and duration of the measures taken in the country, and the justifications put forward by the relevant economic operator. The Ministry shall specify, in particular, whether the product's nonconformity stems from any of the following:

a) The product's failure to meet the essential health and safety requirements specified in Annex 3.

b) Deficiencies in the harmonized standards referred to in the first paragraph of Article 21.

c) Deficiencies in the common characteristics referred to in the third paragraph of Article 21.

(8) Based on the information communicated by the Commission regarding the procedure initiated in the EU market, the Ministry shall, without delay, notify the Commission through the Ministry of Trade of any measures taken regarding the nonconformity of the product covered by this Regulation, any additional information it possesses, and, if it objects to the reported measure, its objections.

(9) If no objection is raised by a Member State or the Commission within three months following receipt of the information referred to in paragraph 6 regarding a provisional measure taken by the Ministry, the measure in question shall be deemed justified.

(10) The Ministry shall ensure, without delay, that appropriate restrictive measures, such as the withdrawal of the product covered by this Regulation from the market, are taken.

(11) The principle of reciprocity shall apply to notifications to be made to the Commission or member states under this article.

Safeguard Measures

ARTICLE 44—(1) If there is an objection from Member States or the Commission regarding the measure specified in the sixth, eighth, and ninth paragraphs of Article 43, or if the Commission finds the measure in question to be contrary to EU legislation, and if, as a result of an investigation conducted by the Commission, it is determined that the measure is not based on justifiable grounds, the Ministry shall revoke the measure.

(2) If the Commission's review determines that the national measure adopted by a Member State is based on valid grounds, the Ministry shall ensure that appropriate restrictive measures—such as a recall from the market—are taken regarding the non-compliant product and shall inform the Commission of the matter through the Ministry of Trade.

Products Covered by This Regulation That Pose a Risk

ARTICLE 45—(1) If, as a result of the assessment conducted pursuant to the first paragraph of Article 43, it is determined that a product covered by this Regulation, despite complying with the essential health and safety requirements specified in Annex 3, poses a risk to human health and safety and, where applicable, to pets or property, and, where applicable, to the environment, the Ministry shall shall require the relevant economic operator, within a reasonable period commensurate with the nature of the risk, to take all appropriate measures to ensure that the product in question no longer poses a risk when placed on the market, or to withdraw or recall the product from the market.

(2) The economic operator shall ensure that all appropriate corrective measures are taken regarding all products covered by this Regulation that it places on the market.

(3) The Ministry shall, through the Ministry of Trade, promptly inform the Commission and the member states, on a reciprocal basis, regarding the product posing a risk as specified in the first paragraph. Such notification shall include all available details, particularly the data necessary to identify the product in question, the product's country of origin and supply chain, the nature of the risk, and the nature and duration of the measures taken in the country.

Nonconformity of Form

ARTICLE 46—(1) Subject to the provisions of Article 43, if any of the following findings are identified regarding a machine or related product, the Ministry shall request the relevant economic operator to remedy such nonconformity:

a) Affixing the "CE" marking in violation of Article 25 or the "CE" Marking Regulation.

b) Failure to affix the "CE" marking.

c) The identification number of the notified body involved in the production control phase being affixed in a manner contrary to the third paragraph of Article 25, or failing to be affixed at all.

(c) Failure to prepare the EU Declaration of Conformity or its incorrect preparation.

d) The technical file is missing or incomplete.

e) The absence, inaccuracy, or incompleteness of the information specified in the sixth paragraph of Article 11 or the third paragraph of Article 14.

f) Failure to comply with any other administrative requirement specified in Articles 11 or 14.

(2) Subject to the provisions of Article 43, if any of the following findings are identified regarding a partially completed machine, the Ministry shall request that the relevant economic operator remedy this nonconformity:

a) Failure to prepare the EU Declaration of Incorporation or its incorrect preparation.

b) The technical file is missing or incomplete.

c) The absence, inaccuracy, or incompleteness of the information specified in the fifth paragraph of Article 12 or the third paragraph of Article 15.

(c) Failure to comply with any other administrative requirement specified in Article 12 or Article 15.

(3) If the non-compliance specified in the first and second paragraphs persists, the Ministry shall take all necessary measures to restrict or prohibit the product covered by this Regulation from being placed on the market, or shall ensure the product is recalled or withdrawn from the market.

CHAPTER EIGHT
Miscellaneous and Final

Provisions Committee Proceedings and Exchange of Experience

ARTICLE 47—(1) The Ministry shall participate in the work of the committee established by the Commission regarding machinery or related products.

(2) The Ministry and the Ministry of Trade shall participate in experience-sharing events organized by the Commission.

Confidentiality

ARTICLE 48—(1) All parties shall, in performing their duties in accordance with this Regulation, treat as confidential any

a) Personal data,

b) and trade secrets and confidential commercial information belonging to natural or legal persons, including intellectual property rights,

shall respect their confidentiality.

(2) Subject to the provisions of the first paragraph, information shared on a confidential basis between authorized institutions and the Ministry, and between the Ministry and the Commission, may not be disclosed without the prior approval of the authorized institution that is the source of the information.

(3) The provisions of the first and second paragraphs do not affect the rights and obligations of the Ministry and accredited organizations regarding the exchange of information and the sharing of warnings, nor do they affect the obligations of relevant persons to provide information under criminal law.

(4) The Ministry may exchange confidential information with regulatory authorities of third countries with which it has bilateral or multilateral confidentiality agreements and arrangements, provided that such agreements and arrangements ensure that any exchange of information is conducted in accordance with the relevant legislation.

Administrative Sanctions

ARTICLE 49—(1) In the event of a violation of the provisions of this Regulation by economic operators, the Ministry shall apply the administrative sanctions set forth in Law No. 7223 against such economic operators in a manner that is effective, proportionate, and deterrent.

Compliance with European Union Legislation

ARTICLE 50—(1) This Regulation has been prepared in accordance with European Union legislation, based on Directive 2006/42/EC of the European Parliament and of the Council, which repeals Directive 73/361/EEC, and Regulation (EU) 2023/1230 of the European Parliament and of the Council of June 14, 2023, (EU) 2023/1230 of the European Parliament and of the Council, which repeals Directives 73/361/EEC and 2006/42/EC, and was prepared within the framework of compliance with European Union legislation.

Repealed Regulations

ARTICLE 51—(1) The following regulations are repealed:

a) The Regulation on the Certification and Marking of Wire Ropes, Chains, and Hooks (73/361/EEC), published in the Official Gazette No. 25155 dated July 1, 2003.

b) The Machinery Safety Regulation (2006/42/EC), published in the Official Gazette No. 27158 dated March 3, 2009.

(2) References to the regulations repealed by the first paragraph shall be deemed to refer to this Regulation.

Transitional Provisions

TRANSITIONAL ARTICLE 1—(1) The Ministry shall not prevent products placed on the market in accordance with the Machinery Safety Regulation (2006/42/EC)—which was repealed by subparagraph (b) of the first paragraph of Article 51—from remaining on the market prior to January 20, 2027. However, effective as of the date of publication of this Regulation, Section 7 of this Regulation shall apply to such products—including those for which proceedings have already been initiated pursuant to Article 12 of the aforementioned Regulation concerning safeguard measures—in lieu of Article 12 of the aforementioned Regulation.

(2) EC type-examination certificates and approval decisions issued pursuant to Article 13 of the Machinery Safety Regulation (2006/42/EC)—which was repealed by Article 51(1)(b)—shall remain valid until their expiration dates.

Entry into Force

ARTICLE 52—(1) The following provisions of this Regulation:

a) Articles 1, 2, and 3; the second and third paragraphs of Article 7; the second and third paragraphs of Article 8; the second paragraph of Article 21; Articles 27 through 42; Article 47, Transitional Article 1, and Articles 52 and 53 shall enter into force on the date of publication;

b) The remaining provisions shall enter
into force on January 20, 2027.

Enforcement

ARTICLE 53—(1) The Minister of Industry and Technology shall enforce the provisions of this Regulation.

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