

Technical Documentation under the EU Machinery Regulation

A white paper on structuring, digitalising and sharing machinery documentation

Summary

From 20 January 2027, Regulation (EU) 2023/1230 generally applies in place of Directive 2006/42/EC. It is directly applicable across the EU, while national rules may still govern matters such as language and workplace use.

For documentation, six things matter most:

1. **Machinery and related products require technical documentation for conformity assessment and instructions and other user information. Partly completed machinery follows a different route: technical documentation, assembly instructions and an EU declaration of incorporation.**
2. **Digital is now allowed, under conditions.** Instructions may be digital, but users must be able to download, print and save them. They must stay online for years, and buyers can still ask for paper.
3. **Documentation must last. Technical documentation, declarations and digital instructions have specific retention or availability requirements, commonly at least 10 years. Certain machine-generated safety records have shorter periods.**
4. **In Denmark, the language is Danish.** Instructions, safety information, warnings on the machine and the EU declaration of conformity must be in Danish.
5. **Machines must be identified and CE marked, subject to applicable marking rules and permitted alternatives for some identification and contact information. Digital instructions must have an indicated access route.**
6. **Substantial modification can create manufacturer duties. Depending on the risk assessment, those duties may concern the affected machine or related product within an assembly; Article 18 also provides an exception for non-professional users modifying products for their own use.**

This paper explains each point in plain language and ends with a checklist of what a documentation platform should offer.

1. From directive to regulation

The Machinery Regulation applies from **20 January 2027** (Art. 54). It replaces the Machinery Directive 2006/42/EC, which has applied since 29 December 2009.

The main difference is legal form: unlike a directive, a regulation applies directly in Member States. Some national measures remain relevant, including language and protection of workers during installation and use (Art. 5).

What Denmark adds. Danish supplementary requirements, including language rules, are addressed in BEK nr. 727 of 13 June 2024, as amended by BEK nr. 486 of 28 May 2026. Other Danish workplace and product rules may also apply. The following national provisions should be checked against the current official texts before publication:

- instructions for use, safety information and the information in Annex III **in Danish** (§ 3). Maintenance instructions for specialist staff mandated by the manufacturer may be in one EU language those staff understand;
- written or spoken information and warnings on the machine **in Danish** (§ 4), with a similar exception for displays used by specialist staff;
- assembly instructions for partly completed machinery in a language accepted by the manufacturer of the machine it will be built into (§ 5);
- the EU declaration of conformity **in Danish** (§ 6), and the EU declaration of incorporation for partly completed machinery **in Danish or English** (§ 7).



Danish penalties and the allocation of market-surveillance responsibilities are governed by national legislation and administrative arrangements. These details should be verified against the current official Danish publications before they are stated as definitive facts.

Amendments since 2023. Always work from the current consolidated text, not the 2023 original. Since publication, the regulation has been:

- corrected, to fix its key dates (corrigendum, OJ L 169, 4 July 2023);
- amended to add emergency rules for crisis-relevant machinery (Regulation (EU) 2024/2748);
- amended to align it with the EU AI Act (Regulation (EU) 2026/1744, the "Digital Omnibus on AI").

The 2024 and 2026 amendments should be considered when consulting the current consolidated text; this paper focuses on the documentation obligations relevant to machinery.

Machines already on the market. Machinery lawfully placed on the market under Directive 2006/42/EC before 20 January 2027 may continue to be made available under the transitional provisions (Art. 52). The new Regulation does not automatically require retrospective recertification of all existing machinery. Later substantial modifications can, however, trigger new manufacturer obligations (Arts. 3(16) and 18).

Scope matters. Article 2 excludes specified categories, including certain electrical products such as electric motors covered by the stated electrical legislation. An excluded component does not automatically exclude machinery incorporating it. Determine the applicable product legislation for each product rather than treating every tagged industrial asset as a separate machine under this Regulation.

Machinery made for own use. The manufacturer definition also covers a person who manufactures machinery and puts it into service for its own use (Art. 3(18)(b)). Industrial companies designing or integrating machinery for internal use should assess whether they take on manufacturer obligations.

2. Who is responsible for what

The regulation assigns duties to manufacturers, authorised representatives, importers and distributors, as well as persons carrying out substantial modifications. It covers machinery, specified related products and partly completed machinery (Art. 2).

Role	Main documentation duties	Where it comes from
Manufacturer (OEM)	Prepare the technical documentation and carry out conformity assessment; issue the EU declaration of conformity, affix CE marking and provide required instructions. Keep technical documentation and declaration for at least 10 years. Take corrective action and notify authorities where required (Art. 10(9)). This also includes manufacturers producing machinery for their own use (Art. 3(18)(b)).	Art. 10, Annex III, Annex IV, Annex V
Manufacturer of partly completed machinery	Prepare the technical file (Annex IV, Part B), the EU declaration of incorporation and the assembly instructions (Annex XI). Keep them for at least 10 years.	Art. 11, Annex IV Part B, Annex XI
Authorised representative	May, by written mandate, keep the technical file and declaration available for the authorities for 10 years. Cannot draw up the technical file.	Art. 12
Importer	Verify conformity assessment, CE marking and required documentation before placing machinery on the market; provide importer contact details, ensure required instructions accompany the product and retain the declaration for 10 years. Do not place known non-compliant machinery on the market; take corrective action and notify authorities where required.	Art. 13 (Art. 14 for partly completed machinery)



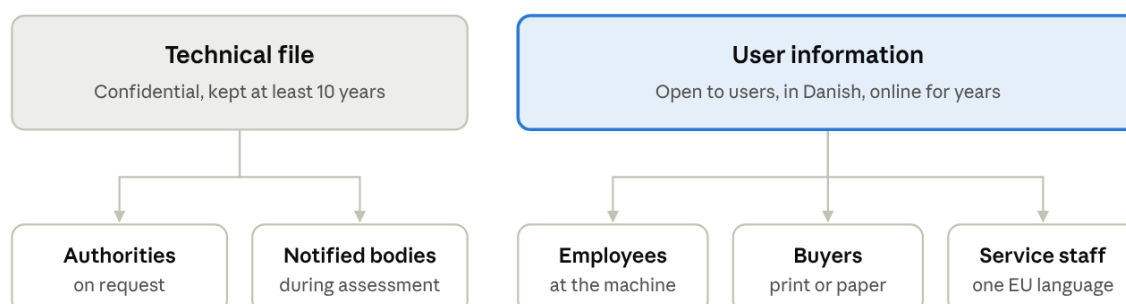
Role	Main documentation duties	Where it comes from
Distributor	Check the CE marking, the declaration, the Danish instructions, and the manufacturer's and importer's markings before selling the machine.	Art. 15 (Art. 16 for partly completed machinery)
Importer or distributor under its own name	Becomes the manufacturer if it sells a machine under its own name or trademark, or modifies it in a way that may affect compliance.	Art. 17
Company that substantially modifies a machine	Generally assumes manufacturer obligations for the affected machinery or related product; an assembly-level risk assessment may limit the scope. Exception for non-professional own-use modification.	Art. 18
Economic operators in the supply chain	Identify economic operators that supplied them and those they supplied, retaining that information for at least 10 years (Art. 19).	Art. 19
Plant operator (the company using the machine)	Keep the instructions in Danish, up to date and easily accessible to employees. Record inspections and keep the results available to Arbejdstilsynet.	Danish working environment rules, BEK nr. 428 of 5 April 2022, §§ 16 and 27 (not the Machinery Regulation)

Modifying machines. A substantial modification is a physical or digital change not foreseen or planned by the manufacturer that creates a new hazard or increases an existing risk and requires the protective measures defined in Art. 3(16). Under Art. 18, the person carrying it out generally assumes manufacturer obligations for the affected product; if only one product in an assembly is safety-affected, the risk assessment may limit those obligations to that product. Non-professional users modifying their own machinery for their own use are excepted under Art. 18. Recording changes and risk assessments is recommended good practice.

3. Two sets of documentation

Machinery and related products generally have technical documentation for conformity assessment and instructions for users. These serve different purposes; separate, access-controlled storage is good practice, not an express requirement of the regulation. Partly completed machinery instead requires the documentation and assembly instructions described in Art. 11 and Annex IV, Part B.

Authorities see the technical file; users get the instructions



The complete technical documentation is generally retained by the manufacturer for competent authorities and, where relevant, notified bodies. The regulation does not categorically prohibit sharing it with users; sharing may be governed by confidentiality and contractual terms. Required user instructions must accompany the product.

	Technical file	User information
Purpose	Shows how the machine meets the safety requirements	Helps people use and maintain the machine safely



	Technical file	User information
Readers	The manufacturer, notified bodies and authorities	Operators, maintenance staff, buyers, service partners
Openness	Not generally required to be supplied to users; available to authorities on reasoned request. Sharing is not categorically prohibited.	Must accompany the machine and be available to everyone who uses it
How long	At least 10 years after the machine is placed on the market or put into service	Digital: online for the expected lifetime and at least 10 years
Language	One the requesting authority can easily understand	Danish in Denmark

What goes in the technical file

Annex IV, Part A lists at least 15 listed elements (as applicable), (a) to (o). In plain terms:

- a complete description of the machine and its intended use;
- the **risk assessment**: which safety requirements apply, how each is met, and which risks remain;
- design and manufacturing drawings and circuit diagrams, and the explanations needed to understand them;
- the harmonised standards or common specifications applied, and the other solutions used where they were not applied;
- calculations, test reports and inspection results;
- how production makes sure every machine matches the design and, for series production, how it stays in conformity;
- a copy of the instructions for use;
- where relevant, declarations for incorporated partly completed machinery and products covered by other EU rules, and their assembly instructions;
- the **source code or programming logic of safety-related software**, when an authority makes a reasoned request;
- where safety-related operations of sensor-fed, remotely driven or autonomous machinery are controlled by sensor data, the applicable descriptions of the system, data, limitations, development, testing and validation (Annex IV, Part A);
- the results of research and tests showing the machine can be assembled and put into service safely.

Partly completed machinery (machines meant to be built into something else) has its own list of 13 elements in Annex IV, Part B. It also needs an EU declaration of incorporation (Annex V, Part B) and assembly instructions (Annex XI).

What goes in the instructions for use

Annex III, section 1.7.4.2 lists 24 items, (a) to (x), that the instructions must cover where applicable. The instructions must also take account of reasonably foreseeable misuse (1.7.4.1). The most important items are:

- the manufacturer's name and full address, and the designation of the machine as marked on it;
- the EU declaration of conformity, or a web address or machine-readable code that leads to it;
- a general description, the intended use, and warnings about known misuse;
- drawings, diagrams and explanations for use, maintenance and repair;
- assembly, installation, putting into service and, if needed, operator training;
- the **remaining risks** and the protective measures and equipment users need;
- what to do in an accident, breakdown or blockage;
- adjustment and maintenance, and how to do them safely;
- which **spare parts** to use where they affect health and safety;
- noise emission values;



- rescue precautions, and information on harmful radiation and hazardous substance emissions where relevant.

Some machine types need extra content. For example, instructions for food and beverage machinery must state recommended products and methods for cleaning, disinfecting and rinsing (Annex III, 2.1.2). Hand-held and mobile machinery must state vibration values (Annex III, 2.2.1.1 and 3.6.3.1).

Sales literature must not contradict the instructions on health and safety, and must give the same emission data (Annex III, 1.7.5).

Marking on the machine

Documentation starts with identifying the product. The following requirements apply as relevant; some information may be provided on packaging or in accompanying documents when direct marking is not possible:

- the model, series or type, year of construction and any existing batch or serial number or other identifying element (Art. 10(5));
- the manufacturer's name and postal address plus a website, email or other digital contact, as a single point of contact (Art. 10(6)). Where this is not possible, the details may go on the packaging or an accompanying document;
- the importer's name and contact details, where there is an importer (Art. 13(3));
- the CE marking, accompanied by the notified body identification number where the applicable conformity-assessment procedure requires it (Arts. 23–25 and the applicable conformity-assessment annexes);
- information and warnings, preferably as symbols or pictograms; written warnings must be in Danish (Annex III, 1.7.1 and BEK 727 § 4);
- how to access the instructions, when they are digital (Art. 10(7)(a)). Additional product-specific Annex III markings may apply, including lifting-related information and explosive-atmosphere marking.

Two rules that apply to both sets

1. **Every document must match the machine.** Instructions must clearly describe the model they belong to (Art. 10(7)), and the declaration of conformity must identify the machine (Annex V).
2. **Keep conformity records accurate. For series production, manufacturers must account for changes to design, production and referenced specifications to maintain conformity (Art. 10(4)); declarations must be kept up to date (Art. 21(2)). Linking document revisions to affected installed machines is recommended good practice, not a universal express requirement for all historical documents.**

4. Going digital

The Machinery Regulation explicitly allows instructions for use to be supplied digitally instead of on paper (Art. 10(7)). The manufacturer must then:

1. **Show the way.** Mark on the machine how to access the digital instructions, for example a web address, a tag number with a web address, or a QR code. If that is not possible, the marking may go on the packaging or an accompanying document.
2. **Make them printable and savable.** Users must be able to download, print and save the instructions on their own device, so they can access them at all times, in particular during a breakdown. This also applies to instructions built into the machine's software.
3. **Keep them online for long enough.** See below.
4. **Provide paper on request.** See below.
5. **Give essential safety information on paper to non-professionals.** If non-professional users could foreseeably use the machine, the safety information essential for putting it into service and using it safely must come on paper.

The instructions must also clearly describe the model they belong to, be in Danish, and be clear, understandable and legible.



How long must instructions stay online?

Digital instructions must be online **during the expected lifetime** of the machine **and for at least 10 years** after it was placed on the market (Art. 10(7)(c)). Both conditions apply, so the **longer period decides**. The two are not added together.

Example: placed on the market in 2027	Expected lifetime	Must stay online until
Brewery filling line	25 years	2052
Small workshop tool	6 years	2037, because the 10-year minimum is longer

The expected lifetime used for online availability should be reasonably substantiated. This is distinct from the general definition of “lifetime” in Art. 3(34). Recording it in the risk assessment or instructions is good practice, but Art. 10(7)(c) does not prescribe a particular field or declaration method. The examples above are illustrative assumptions, not regulatory lifetime values.

The indicated access route must continue to provide the required online availability period. A persistent link, resilient hosting and export or handover arrangements are recommended ways to meet that outcome; the regulation does not prescribe a particular platform architecture.

For partly completed machinery, digital assembly instructions must stay online for at least 10 years after placing on the market (Art. 11(7)(c)); here the regulation does not mention the expected lifetime.

Paper copies within one month

When digital instructions are provided, a user requesting paper instructions at purchase must receive them free of charge within one month (Art. 10(7)). For partly completed machinery, the corresponding request is made by the person incorporating it, for assembly instructions (Art. 11(7)).

The right applies at the time of purchase; the regulation does not oblige the manufacturer to send paper copies years later. The recitals add that the manufacturer should make sure distributors can provide the paper copy, and should consider giving contact details for ordering it by post (recital 40).

The declaration of conformity

The EU declaration of conformity may accompany the machine on paper or be supplied digitally: the instructions then give a web address or a machine-readable code that leads to it (Art. 10(8)). A digital declaration must stay online for the machine's expected lifetime and in any event for at least 10 years after placing on the market or putting into service. It must follow the model in Annex V, Part A, be kept up to date (Art. 21) and, in Denmark, be in Danish (BEK 727 § 6).

Software inside the machine

The regulation also asks more of the machine itself (Annex III, 1.1.9 and 1.2.1):

- software needed to operate safely must be identified, and the machine must be able to show this at all times;
- safety-critical hardware components, software and data must meet the applicable protection requirements against accidental or intentional corruption; Annex III, 1.1.9 also specifies identification and evidence requirements for relevant interventions, without imposing an identical event log on every hardware component;
- where Annex III, 1.2.1 applies, the specified traceability log of interventions and versions of safety-related software uploaded after placing on the market must remain enabled for five years after each upload, for demonstrating conformity upon a reasoned request from a competent authority;
- machinery with fully or partially self-evolving behaviour or logic must record specified safety-related decision data and retain it for one year after collection (Annex III, 1.2.1).



These requirements concern the design and operation of the machinery and its safety-control systems; they do not create a general obligation for every documentation platform to record every software event. The technical documentation should demonstrate how applicable requirements are met.

5. Who gets access to what

Reader	What they get	How and when
Your own employees (operators, maintenance)	Instructions in Danish; inspection results	Workplace accessibility and inspection-record duties arise under applicable Danish workplace rules; separate from the manufacturer's duty to supply instructions (Art. 10(7)).
Buyers and users	Instructions, safety information, declaration of conformity	Digital with download, print and save, or on paper; paper free on request at purchase
The manufacturer's specialist service staff	Maintenance instructions	May be in one EU language they understand (Annex III, 1.7.4)
Market surveillance authorities (in Denmark Erhvervsstyrelsen)	All information and documentation needed to show conformity, including the technical file, the declaration and, if justified, safety software source code and logs	On reasoned request, on paper or digitally, in a language the authority easily understands (Art. 10(3) and 10(10))
Notified bodies	The technical file and production information	During conformity assessment of machinery listed in Annex I (always for Part A; for Part B unless harmonised standards or common specifications covering all relevant requirements are applied) (Art. 25) Notified-body involvement depends on the applicable Art. 25 procedure; it is not universal.
Importers and distributors	The CE marking, declaration of conformity and Danish instructions	Checked before the machine is placed or made available on the market (Art. 13 and 15)
Whoever incorporates partly completed machinery	Assembly instructions and declaration of incorporation	Digital or paper. In Denmark: assembly instructions in a language accepted by the final machine's manufacturer, declaration in Danish or English (Art. 11, BEK 727 §§ 5 and 7)

How long to keep it

What	Minimum period	Source
Technical file and EU declaration of conformity	10 years after placing on the market or putting into service	Art. 10(3)
Digital EU declaration of conformity	Online for the expected lifetime, and at least 10 years	Art. 10(8)
Digital instructions for use	Online for the expected lifetime, and at least 10 years	Art. 10(7)(c)
Technical file and EU declaration of incorporation (partly completed machinery)	10 years; digital assembly instructions and declaration online for 10 years	Art. 11(3), 11(7), 11(8)
Importer's copy of the declaration	10 years	Art. 13(8), 14(7)



What	Minimum period	Source
Notified-body certificates and applicable quality-system records	As specified for the relevant conformity-assessment procedure and responsible party; do not assume a universal period for every record	Art. 25; applicable Annex VII–X provisions
Records of suppliers and customers	10 years	Art. 19
Machine log of interventions and safety-software versions	5 years after each upload	Annex III, 1.2.1
Safety decision data for self-evolving machines	1 year after collection	Annex III, 1.2.1
Inspection results at the workplace	"An appropriate period"	BEK 428 § 27

6. What a documentation platform should offer

A platform can support compliance, but responsibility remains with the relevant economic operator or other responsible person. The table distinguishes regulatory outcomes from useful supporting capabilities; its listed software features are recommendations unless expressly required by the cited provision.

#	Capability	Why it is needed
1	Separate, access-controlled areas for the technical file and the user information, with an export package for authorities	Technical documentation must be available to authorities; segregated access is recommended. (Art. 10(3), 10(7), 10(10), Art. 49)
2	Every document linked to model, serial number and year of construction, with full version history	Product identification and matching instructions are required; full version history is recommended.
3	A permanent web address or lookup, for example by tag number, that keeps working for decades	Online for expected lifetime and at least 10 years, where Art. 10 applies. (Art. 10(7)(c), 10(8))
4	A plan for continuity: data export and hand-over terms if the customer or the vendor leaves	Continuity of access is necessary; export and handover planning are recommended safeguards.
5	Download, print and offline access, including on a phone at the machine	Instructions must be printable, downloadable and savable locally (Art. 10(7)(b)).
6	A language field per document, a check for Danish coverage, and a flag for specialist maintenance instructions	BEK 727 §§ 3–7, Annex III, 1.7.4
7	Retention controls for applicable technical documents; support for machine-generated records only where relevant	Art. 10(3), Art. 19 and Annex III, 1.2.1. Five-year and one-year machine-log requirements do not automatically apply to the documentation platform.
8	Management of declarations of conformity, linked from the instructions	Art. 10(8), Art. 21
9	A completeness check against Annex IV (a)–(o) and Annex III, 1.7.4.2 (a)–(x)	Applicable mandatory elements must be covered; several Annex items are conditional.
10	A change log for machine modifications, with a "substantial or not" assessment	Substantial modification can trigger manufacturer duties, subject to the scope and exception in Art. 18.
11	Print-ready instructions for paper requests	Paper free of charge within one month on request at purchase (Art. 10(7))
12	Inspection and maintenance records available to Arbejdstilsynet	BEK 428 § 27 (outside the Machinery Regulation)



7. Getting ready before January 2027

- ☐ Work out your role for each machine: manufacturer, importer, distributor, authorised representative or operator.
- ☐ For machinery first placed on the EU market or put into service under the new regime from 20 January 2027, check applicable CE marking, instructions and declaration requirements. Purchase date alone does not determine the regulatory regime.
- ☐ Consider separating confidential technical documentation from user information, with suitable access controls (recommended practice).
- ☐ Ensure digital instructions can be downloaded, printed and saved locally, and that access is indicated on the product or as otherwise permitted (Art. 10(7)).
- ☐ Agree how long links and documents will stay available, and what happens if you change supplier.
- ☐ Set up a log of machine modifications, with a safety assessment for each change.
- ☐ Check applicable items in Annex IV and Annex III, 1.7.4.2; not every listed item applies to every product.

Check whether the product falls within Article 2, including applicable exclusions and other EU product legislation.

For machinery manufactured for internal use, assess whether your organisation is the manufacturer under Article 3(18)(b).

Sources

- [Regulation \(EU\) 2023/1230, consolidated version of 27 July 2026 \(EUR-Lex\)](#) (the supplied consolidated PDF is a documentation tool; authentic acts are published in the Official Journal).
- [BEK nr. 727 of 13 June 2024, Danish supplementary rules \(Retsinformation\)](#)
- [BEK nr. 486 of 28 May 2026, amending BEK nr. 727 \(Retsinformation\)](#)
- BEK nr. 428 of 5 April 2022 on the use of technical equipment (verify current consolidated text at Retsinformation)
- [Erhvervsstyrelsen: Market surveillance](#)
- [European Commission: Machinery](#)

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