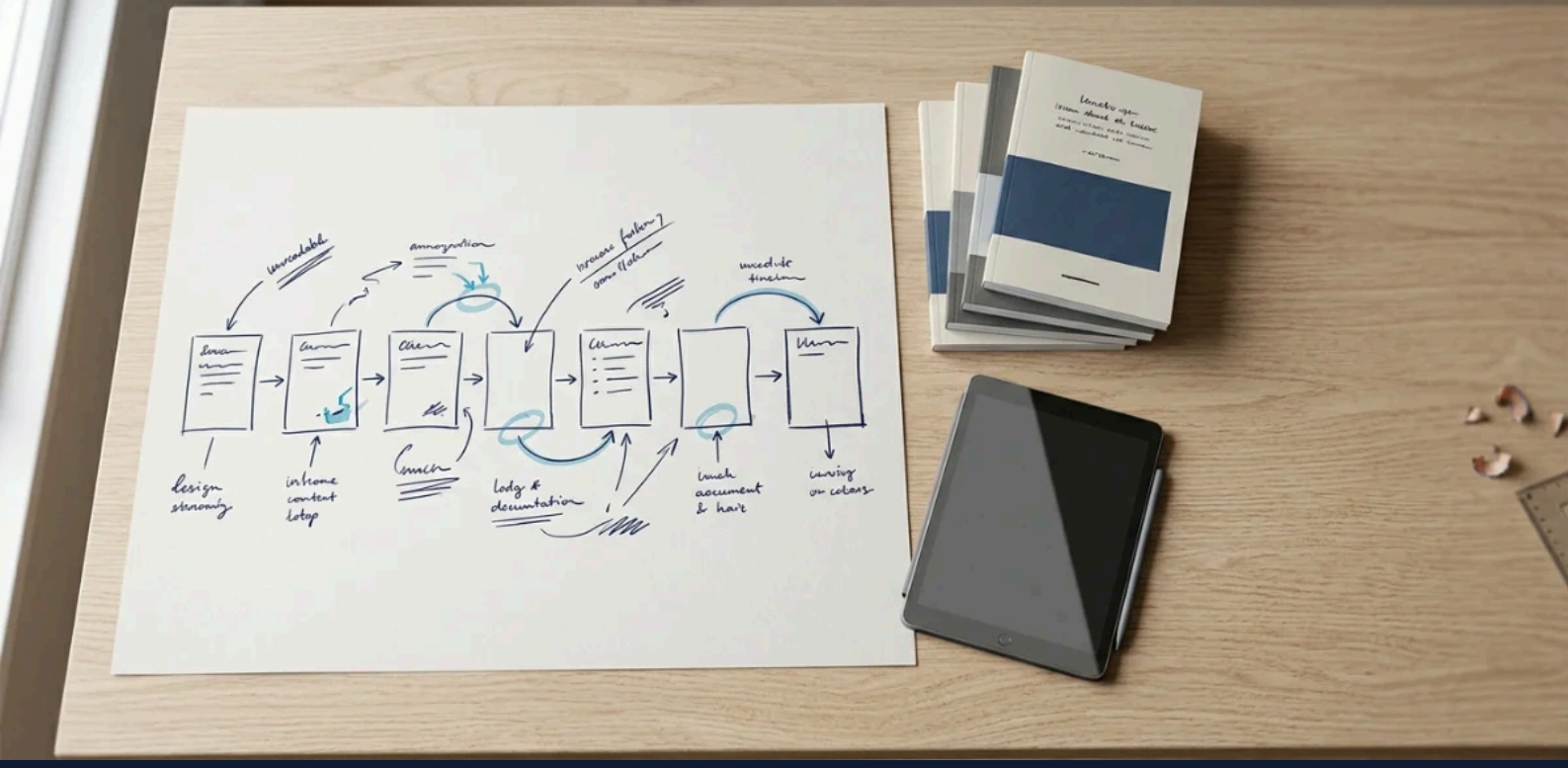

YDNTFY

IMPLEMENTATION GUIDE

REGULATION (EU) 2021/2226

From paper to eIFU: an implementation guide

A step-by-step guide to switching from paper instructions to electronic ones, with the article behind every condition.

LAST REVIEWED

15 September 2026

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AUDIENCE

Regulatory, quality and IT teams

Paper instructions are now optional for most professional devices

Paper instructions for use are printed ahead of time and packed with the device at the production site. By the time a revision is approved, earlier versions are still sitting in warehouses and distributor stock.

Since July 2025, Regulation (EU) 2021/2226 allows electronic instructions for almost every device intended for professional use, not only the short list of device types it originally named. The conditions are set out in Articles 4 to 7, and each one can be answered from the text of the regulation.

Meeting them comes down to seven decisions. This guide works through them in the order they depend on each other, with the article behind each one, so regulatory, quality and IT teams can plan the switch from one document.

Two common misconceptions

“Paper is still mandatory in practice.”
Not since the 2025 amendment, for almost every professional-use device that meets the conditions in Articles 4 to 7. Paper remains required where use by lay persons is reasonably foreseeable, and on request for every device (Steps 1 and 5).

“Switching needs a lengthy notified body submission.”
There is no separate eIFU approval. The provision that suggested one, Article 8, was deleted in 2025, and the review it described was always part of conformity assessment. Most Class I devices self-certify; where a notified body is involved, it is informed through the channel your certificate already requires (Step 7).

The sequence at a glance

STEP	DECISION	WHAT IT SETTLES	WHERE IT COMES FROM
1	**Confirm the device qualifies**	Whether paper can be replaced at all, and for which part of the instructions	Articles 3 to 5
2	**Complete the risk assessment**	What stays on paper, the period set for paper on request, and whether any market needs an exception	Article 4, Article 5(1) and (2)
3	**Choose where the instructions will live**	The address that has to stay stable and accessible for 10 or 15 years	Article 7
4	**Update labelling and packaging**	How the label tells the user the instructions are electronic and how to reach them	Article 6
5	**Build the paper-on-request process**	A no-cost route to paper within the assessed period, seven calendar days at the latest	Article 5(3)
6	**Register the address in EUDAMED**	A UDI database entry, mandatory for MDR devices with electronic instructions	Article 7(3)
7	**Route the change through your quality system**	Conformity assessment, not a standalone eIFU submission	Recital 7 of Regulation (EU) 2025/1234

Table 1 — The seven decisions, in the order they unlock each other.

Where the request comes from, and what it costs before it saves anything

The question can come from more than one direction. Regulatory affairs may raise it after a scope change makes more of the portfolio eligible, such as the one in July 2025. Supply chain or operations may raise it looking for savings on printing, warehousing, and outbound logistics. A sustainability team may raise it as part of a broader push to reduce printed material. A distributor, an authorised representative, or a notified body observation can prompt the same question from outside the company. Whichever direction it comes from, the sequence below is the same.

The decision to start is a business one, not a regulatory one. The risk assessment in step 2 tests whether electronic instructions are as safe as paper for a given device. It does not test whether the switch is worth doing financially. That is a separate question, worth answering first.

WHAT IT COSTS

- The risk assessment itself, and keeping it current as products or markets change
- New labelling artwork, and the validation cycle any label change already requires
- A hosting platform that meets the conditions in Article 7, including the ten or fifteen year commitment
- A paper-on-request process that keeps working for as long as the instructions do

WHAT IT CAN OFFSET

- ✓ No routine printing of instructions, and no reprinting when they change
- ✓ No handling cost for adding printed instructions to every box at the production site
- ✓ Smaller packaging where the printed instructions determined the box size
- ✓ One current version on a website, rather than multiple printed batches already in the supply chain
- ✓ No obsolete printed stock to scrap when a version is superseded
- ✓ A correction that reaches every user as soon as it is published, rather than only from the next print run onward

Which side is larger depends on the portfolio, the markets it sells into, and what the packaging and logistics already cost. Nothing in the regulation puts a number on either side, and neither does this guide.

Who has to be in the room

The decisions below sit in different departments, and none of the people who own them holds all the information the sequence needs.

DECISION	USUALLY OWNED BY	NEEDS INPUT FROM
Confirm the device qualifies	Regulatory affairs	Quality, for the retention and quality-system consequences of a yes
Complete the risk assessment	Regulatory affairs	Production and supply chain, for the environment and access conditions; whoever will fulfil paper requests, for a realistic period
Choose where the instructions will live	IT, or whoever runs the website	Regulatory affairs, which sets the retention period the platform has to meet
Update labelling and packaging	Labelling or packaging	Regulatory affairs, for the content; quality, for the validation
Build the paper-on-request process	Customer service or logistics	Regulatory affairs, for the period; production, for the print-ready files
Register the address in EUDAMED	Regulatory affairs	IT, since the address has to already be live and correct before it is filed
Route the change through your quality system	Quality, or the notified body liaison	Regulatory affairs

Table 2 — Ownership and dependencies across the seven decisions.

One-directional, not shared

IT cannot choose a platform before regulatory affairs fixes how long it has to run for. Regulatory affairs cannot finish the risk assessment without knowing what production and supply chain can actually support. Getting the people who hold that information into the same conversation before the risk assessment is written is what keeps the sequence from needing to be redone.

1 Qualify · 2 Risk assessment · 3 Hosting · 4 Labelling · 5 Paper on request · 6 EUDAMED · 7 Quality system

Step 1: Confirm the device qualifies

Eligibility is a pass-or-fail test with six parts. Five of the six are pass or fail; the sixth, on lay use, decides which part of the instructions has to stay on paper rather than whether the device is eligible at all.

GATE	QUESTION	ARTICLE
1	**Are instructions for use required at all?** Class I and IIa devices that can be used safely without them are excepted.	MDR Annex I, Ch. III, 23.1(d)
2	**Is the product a device under the MDR?** In vitro diagnostics carry their own, differently worded permission.	MDR Art. 1(4); IVDR Annex I, 20.1(f)
3	**Is it intended for use by professional users?** Defined as persons using the device in the course of their work in a professional healthcare activity.	Art. 3(1); Art. 2(2)
4	**Is use by lay persons reasonably foreseeable?** If so, the lay-facing instructions stay on paper; the professional instructions may remain electronic.	Art. 3(2)
5	**Does the risk assessment demonstrate that safety is maintained or improved?**	Art. 4 and 5(1)
6	**Can the conditions in Articles 5 to 7 be held for the full 10 or 15 years?**	Art. 5, 6 and 7

Table 3 — The six eligibility gates.

Run the test per device family rather than once for the whole portfolio. Two products held under the same quality system can land on different answers, particularly at gate 4. The full reasoning behind each gate, including the mixed-use and legacy-device edge cases, is in the eIFU eligibility page; this table is the summary a project plan can work from directly.

1 Qualify · 2 **Risk assessment** · 3 Hosting · 4 Labelling · 5 Paper on request · 6 EUDAMED · 7 Quality system

Step 2: Let the risk assessment answer more than a safety question

The risk assessment is not a formality that follows a decision already made. It is the document the rest of the project is built on. Article 4(1) requires it to cover **at least** the following eleven elements: a floor, not a checklist to be shortened.

POINT	WHAT IT COVERS
(a)	Knowledge and experience of the intended users, in particular regarding use of the device and user needs
(b)	Characteristics of the environment in which the device will be used
(c)	Knowledge and experience of the intended user of the hardware and software needed to display the instructions
(d)	Access of the user to the reasonably foreseeable electronic resources needed at the time of use
(e)	Performance of safeguards protecting the electronic data and content from tampering
(f)	Safety and back-up mechanisms in the event of a hardware or software fault
(g)	Foreseeable medical emergency situations requiring information in paper form
(h)	Impact of the temporary unavailability of the website, or of the internet generally, including in the healthcare institution, and the safety measures available
(i)	Evaluation of the period within which paper instructions have to be provided at the user's request
(j)	Assessment of the website's compatibility with the different devices that could be used to display the instructions
(k)	Management of different versions of the instructions, in accordance with Article 5(8)

Table 4 — The eleven elements of Article 4(1).

Three of these tend to be decisive in practice: (b), the environment; (d), access to the electronic resources needed at the time of use; and (g), the emergency situations that keep some information on paper regardless of how good the electronic system is. Point (i) is the one that fixes an operational number: the period within which paper reaches someone who asks for it, capped by Article 5(3) at seven calendar days at the latest.

⚠ Neutral is not enough

The assessment has to demonstrate something specific, not just document the eleven points: that providing instructions electronically **maintains or improves** the level of safety obtained on paper (Article 5(1)). A neutral or inconclusive assessment does not satisfy this; the demonstration has to go one way.

Two further conditions are fixed here rather than later.

ARTICLE 5(2)

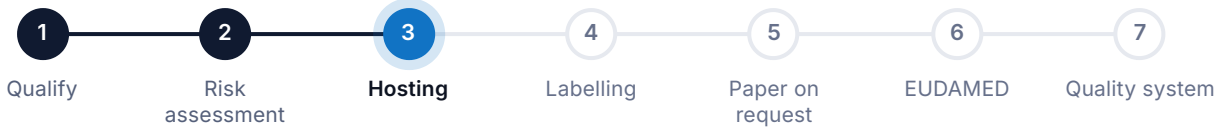
Market-by-market coverage

Electronic instructions have to be offered in every Member State where the device is made available or put into service, unless duly justified in the risk assessment itself. The derogation exists, but it has to be argued and documented, not assumed.

ARTICLE 5(11)

Language

The instructions are available on the website in an official language of the Union, determined by the Member State in which the device is made available. The Member State picks among Union languages; the manufacturer does not choose a language at large.



Step 3: Choose where the instructions will live

Not every manufacturer needs a website for the same reason. Article 7(1) applies the website duty specifically to two situations: instructions supplied on an electronic storage medium together with the device, and devices fitted with a built-in system that visually displays the instructions. In practice, most manufacturers choosing eIFU fall into one of these, because a website is how the instructions actually reach the user.

The website itself has to meet five conditions under Article 7(2).

POINT	REQUIREMENT
(a)	**Format.** A commonly used format, readable with freely available software
(b)	**Tamper protection.** Protected against unauthorised access and tampering, in accordance with the Article 4(1)(e) safeguards
(c)	**Uptime.** Server downtime and display errors reduced as far as possible
(d)	**Data protection.** Compliant with the GDPR
(e)	**Address stability.** The internet address, as displayed under Article 6(2), stays stable and directly accessible for the whole of the Article 5(9)/(10) retention period

Table 5 — The five website conditions of Article 7(2).

Condition (e) is the one that shapes the platform decision, because it is not open-ended: it runs for a fixed number of years set by two other provisions.

ARTICLE 5(9)	ARTICLE 5(10)
10 years	**15 years**
Devices with a defined expiry date, implantables excepted: 10 years after the last device is placed on the market, and at least 2 years after the end of the expiry date of the last produced device.	Devices without a defined expiry date, and all implantable devices: 15 years after the last device is placed on the market.

Table 6 — The two retention periods the address has to survive.

That length of commitment is the reason the choice of domain matters as much as the choice of platform. An address that sits on a vendor's domain ties a statutory duty to a commercial relationship that can end; the same question has already come up in relation to an authorised representative's domain.

A vendor's domain is not a neutral technical choice, it is a lock-in mechanism.

That includes the eIFU hosting vendor itself, should you decide to use one. Switching vendors later would mean re-labelling every device already on the market to point at a new address. The domain has to belong to the manufacturer, not whoever is hosting it. A domain the manufacturer controls, pointed at whatever platform is running underneath it, is what keeps the choice of vendor reversible.

The platform also has to satisfy Article 5(13): every issued version and its date of publication stays available throughout the retention period, with obsolete versions available on request. That is a record-keeping duty as much as a hosting one, and it has to be designed in from the start rather than added once a correction is needed.

Step 4: Update labelling and packaging

Article 6 sets out what the label has to say, in three layers.

First, the label states the fact. Manufacturers clearly indicate on the label that the instructions are supplied electronically instead of on paper (Article 6(1)). That information goes on the unit packaging or, where appropriate, the sales packaging; for fixed installed devices it also goes on the device itself, and for software, at the point access is granted.

Second, access information is provided, in the same place or, if that is not practicable, in a paper document supplied with each device (Article 6(2)).

Third, that access information carries four specific items (Article 6(3)):

POINT	ITEM
(a)	Any information needed to view the instructions
(b)	The Basic UDI-DI and/or UDI-DI, plus any additional identifying information such as the device's name and, if applicable, its model
(c)	Relevant manufacturer contact details: name, address, email or other online contact, and website
(d)	Where and how paper instructions can be requested, and within what time they will be provided at no additional cost, per Article 5(3)

Table 7 — The four items of access information under Article 6(3).

DELETED IN 2025

A fourth paragraph, which required implant IFUs to keep a patient-facing part on paper regardless, was deleted in 2025 (Article 6(4)); the general lay-person rule in Article 3(2) now covers that ground instead.

ARTICLE 6(5)

The electronic instructions have to be available **entirely as text**, which may contain symbols and graphics, carrying at least the same information as the paper version. Video or audio may be added, never in place of the text.

New artwork for all of this goes through the same validation cycle as any other label change. It is familiar work rather than new work, and it is usually where real lead time sits.

THE PACKAGING ANGLE

Removing printed instructions for use from the box can shrink the packaging a device needs. From 1 January 2030, Regulation (EU) 2025/40 (PPWR) requires packaging to be designed with its weight and volume reduced to the minimum necessary for its function. Whether eIFU changes a given package's dimensions depends on whether the printed instructions were driving the box size in the first place. PPWR doesn't create a duty specific to eIFU, but a smaller package is one way the switch can help meet an obligation that applies regardless.

Where a switch does shrink a package, that's a packaging-engineering change as much as a labelling one. The team already responsible for packaging needs to be involved from the start, not brought in once a new box size is decided.

1 Qualify · 2 Risk assessment · 3 Hosting · 4 Labelling · **5 Paper on request** · 6 EUDAMED · 7 Quality system

Step 5: Build the paper-on-request process

Article 5(3) is short but operational: a system to provide paper at no additional cost, within the period the risk assessment set, and at the latest within seven calendar days of the request, or at the time of delivery if the request is made at the time of order.

This is closer to a fulfilment process than a legal one. Three things have to work together: who takes the request, where the print-ready file lives and how current it is, and how quickly it can be produced and shipped. The duty does not end once the electronic version is live; it runs for as long as the instructions do.

THE CAP

7 days

Calendar days, at the latest. The risk assessment may set a shorter period, never a longer one.

⚠ **One duty sits on paper regardless**

Article 5(4) requires information on foreseeable medical emergency situations to be provided on the device or on a leaflet, and, for devices with a built-in display, information on how to start the device. That information is not part of the paper-on-request system; it travels with the device unconditionally.

1 Qualify · 2 Risk assessment · 3 Hosting · 4 Labelling · 5 Paper on request · 6 EUDAMED · 7 Quality system

Step 6: Register the address in EUDAMED

Article 7(3) requires the internet address to be given to the UDI database, at the latest from the date device registration applies under MDR Article 123(3), point (d) or (e). For a manufacturer providing electronic instructions under the MDR, this entry is mandatory, even though the underlying field, Annex VI Part B point 22, is marked "(optional)" in the annex itself, because it was drafted to cover a more general case. The equivalent IVDR field, point 19, stays optional in every case: the eIFU regulation makes no reference to the IVDR at all.

Once filed, the entry is not a one-time task.

DUTY	WHAT IT REQUIRES	WHERE IT COMES FROM
Periodic verification	Manufacturers periodically verify the correctness of all data relevant to devices they have placed on the market	MDR Annex VI, Part C, 5.4
Timely update	Any change to an element that does not require a new UDI-DI has to be updated within 30 days	MDR Annex VI, Part C, 5.8

Table 8 — Keeping the registered address correct.

ON THE REGISTRATION DEADLINE

The transition triggered by Commission Decision (EU) 2025/2371 sets the first four EUDAMED modules as mandatory six months after the notice, landing on 28 May 2026, with a second deadline twelve months after the same notice for devices already on the market. Published sources disagree on whether that second date falls on 27 or 28 November 2026, so plan against the earlier of the two. The full field-by-field analysis is its own piece.

1 Qualify · 2 Risk assessment · 3 Hosting · 4 Labelling · 5 Paper on request · 6 EUDAMED · 7 **Quality system**

Step 7: Route the change through your existing quality system

There is no standalone eIFU submission to make. Treat the move to electronic instructions as the kind of change your existing procedures are already built to catch. Where a notified body is part of your conformity assessment, involve it the same way any comparable instructions or label change already requires.

Concretely, that touches three places already in your QMS.

EXISTING QMS ELEMENT	WHAT CHANGES
Design change control (e.g. ISO 13485 §7.3.9)	Open it the way a label or instructions update already requires; file the Article 4 risk assessment and the Article 5(5) validation evidence there rather than as stand-alone documents
Document control	Update the technical documentation and label templates for electronic delivery plus the paper-on-request fallback
Notified body notification	Necessary only if one is involved in your conformity assessment; where it is, inform it through the channel your certificate already requires

Table 9 — Where an eIFU change lands inside an existing quality system.

This step only applies once a notified body is involved at all. Article 52(7) lets most Class I devices self-certify: the manufacturer draws up its own technical documentation and EU declaration of conformity, and no notified body reviews any of it.

THE THREE CLASS I EXCEPTIONS

Sterile devices, devices with a measuring function, and reusable surgical instruments. Even then, the notified body's involvement is limited to a narrow slice: sterility for the first, metrology for the second, reuse-related aspects for the third (Article 52(7)(a)-(c)). That third category's slice explicitly includes the instructions for use. In practice, an eIFU change is unlikely to touch what a notified body reviews for a sterile or measuring Class I device, but for a reusable surgical instrument, it does.

For every device on Annex IX, X or XI (Class IIa, IIb, III, and the three Class I exceptions above), notifying the notified body is not optional. Informing them of a change that could affect safety, performance or the conditions of use is already a standing duty. An eIFU switch is exactly that kind of change.

The exact clause depends on your conformity assessment route. MDR Annex IX, point 2.4, covers changes to the quality management system or device range under the most common route. Annex IX, point 4.10, covers changes to the device itself where a technical documentation assessment certificate is also held. Annex X, point 5.1, carries the equivalent duty under type-examination. The pattern is consistent even though the numbering isn't: your QMS almost certainly already has a way to tell your notified body about a change like this.

That has been true since before Article 8 was deleted in 2025, not only after. Until then, Article 8 stated that compliance with Articles 4 to 7 would be reviewed by a notified body during the procedure applicable for conformity assessment under the MDR. In other words, that review was already inside conformity assessment, not alongside it. The 2025 amendment removed the article; the recital explaining the change describes it as removing a requirement that duplicated something the MDR's own conformity assessment rules already covered. Deleting the article changed nothing about what gets reviewed.

After the first device family

Running one device family through this sequence before extending it to the rest of the portfolio is a practical choice rather than a legal one. The eligibility and risk-assessment questions can land differently for different products, and a single family is what actually tests the process, not only the paperwork.

From there, three duties run continuously rather than closing out at go-live.

DUTY	REQUIREMENT	ARTICLE
Version history	Every issued version and its date of publication stays available through the retention period; obsolete versions on request	5(13)
Revision notice	Users are told when a revision is made for safety reasons	5(8)
EUDAMED accuracy	The registered address stays correct as anything about the device or the address changes	Annex VI, Part C, 5.4 and 5.8

Table 10 — The three continuous duties after go-live.

What the regulation fixes is the questions themselves, which is what makes this a project with an end.

None of the seven decisions above is optional, and none of them is quick. How long any one takes depends on the product portfolio and the quality system already in place, and nothing in the regulation fixes that. Once the risk assessment is written, every decision after it follows from what that assessment says.

About this guide

Ydntfy hosts electronic instructions for use for medical device manufacturers, built to the conditions in Articles 4 to 7 of Regulation (EU) 2021/2226, including the fixed-term hosting described under "Choose where the instructions will live." You can see how it works at ydntfy.com.

Contact

Questions about your own portfolio, or want the eligibility assessment walked through with your team?

info@ydntfy.com

Sources

Every article reference is checked against the consolidated text of the regulations in force (verified 3 September 2026 against **REG-002C**, the eIFU regulation as consolidated to 16 July 2025, and **REG-004C**/**REG-005C**, the MDR and IVDR as consolidated to 1 January 2026 and 10 January 2025 respectively).

1. **Commission Implementing Regulation (EU) 2021/2226** of 14 December 2021, as amended by Regulation (EU) 2025/1234, laying down rules for electronic instructions for use of medical devices, OJ L 448, 15.12.2021. eur-lex.europa.eu/eli/reg_impl/2021/2226/oj
   Article 3(1) and (2); Article 4(1), points (a) to (k), and 4(2); Article 5, points (1), (2), (3), (4), (8), (9), (10), (11) and (13); Article 6(1), (2), (3) with points (a) to (d), and (5); Article 7(1), (2) with points (a) to (e), and (3).

2. **Commission Implementing Regulation (EU) 2025/1234** of 25 June 2025, OJ L, 26.6.2025. eur-lex.europa.eu/eli/reg_impl/2025/1234/oj
   Article 1, deletion of Article 6(4), Article 8 and Article 5, point (12); recital 7, on the reason for the Article 8 deletion.

3. **Regulation (EU) 2017/745 on medical devices (MDR)**: Article 1(4) and 1(6)(a); Annex I, Chapter III, 23.1(d); Article 34(3); Article 123(3), points (d) and (e); Annex VI, Part B, point 22, and Part C, points 5.4 and 5.8; Annex IX, points 2.4 and 4.10, and Annex X, point 5.1, on notifying a notified body of a change; Article 52(7), points (a) to (c), on which Class I devices self-certify and the limited scope of notified body involvement for the rest. eur-lex.europa.eu/eli/reg/2017/745/oj

4. **Regulation (EU) 2025/40 on packaging and packaging waste (PPWR)**: Article 2(1), on scope; Article 10(1), on the packaging minimisation duty applying from 1 January 2030. eur-lex.europa.eu/eli/reg/2025/40/oj

5. **ISO 13485:2016**, clause 7.3.9 (design and development changes), referenced as a common example of where this change is typically handled inside a manufacturer's quality management system. The MDR does not name ISO 13485 specifically; conformity with it is the usual, not the only, way to meet Article 10(9)'s quality management system requirement.

6. **Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)**: Annex I, Chapter III, 20.1(d) and (f). eur-lex.europa.eu/eli/reg/2017/746/oj

7. **Commission Decision (EU) 2025/2371**, OJ 27 November 2025, on the EUDAMED registration timing referenced in Article 7(3) and MDR Article 123(3)(d)-(e). Exact second-deadline date under verification (see the note in Step 6).