eIFU ELIGIBILITY WORKSHEET

The six eligibility gates, and the decision behind each one

Eligibility for electronic instructions for use is decided by six questions. They are drawn from Commission Implementing Regulation (EU) 2021/2226, as amended by Regulation (EU) 2025/1234, and from Annex I of the MDR. This worksheet sets them out in the order they are worth answering, with room to record the answer as it is formed.

The test changed on 16 July 2025. The former list of three device categories was replaced by a test based on who uses the device. Five of the six gates are pass or fail. Gate 4 determines which document has to remain on paper, rather than whether the device is eligible at all.

HOW TO USE IT	SCOPE	VERSION
Run it per device family. Record the reasoning, not a yes.	Devices under Article 1(4) of the MDR. IVDs follow Annex I, 20.1(f) of the IVDR.	1.0, 18 August 2026. Law as it stood on that date.

1 **Are instructions for use required at all?** — MDR Annex I, 23.1(d)
Where none are required, there is nothing to publish in electronic form.

2 **Is the product a device under the MDR?** — MDR Article 1(4)
Medical devices, accessories and Annex XVI products. In vitro diagnostics follow the IVDR.

3 **Is the device intended for use by professional users?** — Articles 3(1), 2(2)
The provision that replaced the former list of three device categories.

4 **Is use by lay persons reasonably foreseeable?** — Article 3(2)
Determines which document stays on paper, rather than whether the device qualifies.

5 **Does the risk assessment support the electronic form?** — Articles 4, 5(1)
Eleven elements are the statutory floor, and the conclusion is what has to be recorded.

6 **Can the conditions be held for 10 or 15 years?** — Articles 5, 6, 7
Operational rather than legal, and the gate that outlasts the decision.

Before you start

Run the tree per device family rather than once for the company, because gates 4, 5 and 6 can produce different results for products held under the same quality system. Record the reasoning at gates 3 and 4 as it is formed, since both are positions that may have to be defended during conformity assessment. Resolve gate 6 before selecting a solution, as it concerns a commitment measured in years rather than a decision taken now.

Qualifying is not the same as being obliged. Regulation (EU) 2025/1234 permits electronic instructions for professional-use devices, and the paper-on-request duty applies either way.

Once a device passes. The twenty-five conditions of Articles 4 to 7, with the document that demonstrates each one, are set out in the eIFU compliance checklist at ydntfy.com/en/resources/eifu-notified-body-website-checklist/

CAN THIS DEVICE GO PAPERLESS?

Electronic instructions for use in the EU

Regulation (EU) 2021/2226 as amended by Regulation (EU) 2025/1234.
Gates 1, 2, 3, 5 and 6 are pass or fail. Gate 4 determines which document remains on paper.

1 Does the device need instructions for use at all?

NO → No instructions are required, so there is nothing to publish. Class I and IIa devices usable safely without them are excepted (Annex I, 23.1(d) MDR).

YES ↓

2 Is it a device under the MDR?

NO → In vitro diagnostics fall under the IVDR: professional use only, and excluded for near-patient testing (Annex I, 20.1(f) IVDR).

YES ↓

3 Is it intended for use by professional users?

NO → Only professional-use devices may go electronic (Article 3(1)). A lay-user device keeps its paper instructions (Annex I, 23.1(d) MDR).

YES ↓

4 Is use by lay persons reasonably foreseeable?

YES → The instructions written for lay persons are provided on paper. The professional instructions may remain electronic (Article 3(2)).

NO ↓

5 Does your risk assessment show safety is maintained or improved?

NO → Not established. The electronic form is not appropriate for this device until the assessment supports it (Articles 4 and 5(1)).

YES ↓

6 Can you hold the conditions for the full 10 or 15 years?

NO → Retention, paper on request, language, label and website requirements apply for the whole period (Articles 5, 6 and 7).

YES ↓

Electronic instructions for use are permitted for this device.

Separate route: software
MDR software may deliver its instructions through itself (Art. 3(3)).

A paper copy remains available on request throughout the retention period (Article 5(3)).

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1 Are instructions for use required at all?

MDR ANNEX I, 23.1(D)

Instructions for use are in principle supplied with a device. Class I and class IIa devices that can be used safely without them are excepted, subject to the other provisions of that Section. This gate is first because it can remove part of a portfolio at no cost.

- [ ] Instructions required, continue
- [ ] Not required, the review ends here

REASONING AND DOCUMENT REFERENCE

2 Is the product a device under the MDR?

MDR ARTICLE 1(4)

Regulation (EU) 2021/2226 is an implementing regulation made under the MDR. Device means medical devices, accessories for medical devices and the products listed in Annex XVI. Devices supplied under the transitional provisions of Article 120 of the MDR are covered as well, according to recital 3 of Regulation (EU) 2025/1234. In vitro diagnostics fall outside this regulation and carry their own permission under the IVDR.

- [ ] Medical device or accessory
- [ ] Annex XVI product
- [ ] Article 120 legacy device
- [ ] IVD, follow IVDR Annex I, 20.1(f)

REASONING AND DOCUMENT REFERENCE

3 Is the device intended for use by professional users?

ARTICLES 3(1), 2(2)

Professional users are persons using the device in the course of their work in the framework of a professional healthcare activity. The question is the capacity in which the device is handled, rather than the identity of the purchaser. Where a device is intended for lay users, the instructions remain on paper.

- [ ] Intended for professional users
- [ ] Intended for lay users, paper remains

INTENDED PURPOSE STATEMENT AND REFERENCE

4 Is use by lay persons reasonably foreseeable?

ARTICLE 3(2)

Where it is reasonably foreseeable that a device intended for professional users is also used by lay persons, the instructions intended for lay persons have to be provided in paper form. The provision operates on the instructions rather than on the device, so foreseeable lay use no longer removes the device from scope. The distinction assists only where the clinical document and the lay-facing document exist separately.

- [ ] Lay use not foreseeable
- [ ] Foreseeable, separate lay document printed
- [ ] Foreseeable, single document, printed in full

WHICH DOCUMENT STAYS ON PAPER, AND WHY

5 Does the risk assessment support the electronic form? ARTICLES 4, 5(1)

Gates 1 to 4 establish that electronic instructions are permitted. They do not establish that the electronic form is appropriate for the device in question. The assessment has to cover at least these eleven elements, so the list is a floor rather than a closed set. Points (b), (d) and (g) tend to decide the outcome.

- [ ] **Knowledge and experience of the intended users,** in particular regarding the use of the device, and user needs. — Article 4(1)(a)
- [ ] **Characteristics of the environment in which the device will be used.** Conditions in an operating theatre with a shared terminal differ materially from those in pre-hospital care. — Article 4(1)(b)
- [ ] **Knowledge and experience of the intended user of the hardware and software** needed to display the instructions in electronic form. — Article 4(1)(c)
- [ ] **Access of the user to the reasonably foreseeable electronic resources** needed at the time of use. Where a screen cannot be reached at the moment the instruction is needed, the assessment will show it. — Article 4(1)(d)
- [ ] **Performance of the safeguards** ensuring that the electronic data and content are protected from tampering. — Article 4(1)(e)
- [ ] **Safety and back-up mechanisms** in the event of a hardware or software fault, particularly where the instructions are integrated within the device. — Article 4(1)(f)
- [ ] **Foreseeable medical emergency situations** requiring the provision of information in paper form. Some information remains printed irrespective of the quality of the electronic system. — Article 4(1)(g)
- [ ] **Impact of temporary unavailability** of the website or of the internet, or of access to it in the healthcare institution, and the safety measures available to cope with that. — Article 4(1)(h)
- [ ] **Evaluation of the period within which paper will be provided** at the user's request. The period is for the manufacturer to justify, subject to the outer limit of 7 calendar days at Article 5(3). — Article 4(1)(i)
- [ ] **Assessment of the website's compatibility** with the different devices that could be used to display the instructions. — Article 4(1)(j)
- [ ] **Management of different versions** of the instructions, where applicable in accordance with Article 5(8). — Article 4(1)(k)
- [ ] **A process to update the assessment** in view of the experience gained in the post-marketing phase. — Article 4(2)
- [ ] **The conclusion recorded:** the electronic form maintains or improves the level of safety obtained on paper. This is the output the gate turns on. — Article 5(1)

RISK ASSESSMENT REFERENCE AND REVISION

What remains on paper ARTICLE 5

A device that passes all six gates still carries some printed material.

- [ ] **A paper copy on request,** at no additional cost, within the period set in the risk assessment and at the latest within 7 calendar days. — Article 5(3)
- [ ] **Information on foreseeable medical emergency situations,** provided on the device or on a leaflet. — Article 5(4)
- [ ] **The access information,** on the packaging or, where that is not practicable, in a paper document supplied with each device. — Article 6(2)

6 Can the conditions be held for 10 or 15 years?

ARTICLES 5, 6, 7

The final gate is operational rather than legal. Article 7(2)(e) is the condition least likely to be satisfied by a document hosted on a general marketing website, because the address is fixed for the retention period rather than for the life of the current site.

- [ ] **Retention of 10 years** after the last device has been placed on the market, for devices with a defined expiry date other than implantables, and at least 2 years after the end of the expiry date of the last produced device. — Article 5(9)
- [ ] **Retention of 15 years** after the last device has been placed on the market, for implantable devices and for devices without a defined expiry date. — Article 5(10)
- [ ] **Paper on request,** at no additional cost, for as long as the retention period runs. — Articles 5(3), 5(9), 5(10)
- [ ] **Availability in every Member State** where the device is made available or put into service, in an official language of the Union determined by that Member State, unless duly justified in the risk assessment. — Articles 5(2), 5(11)
- [ ] **Version history** for the retention periods, carrying the date of publication of each electronic version, with obsolete versions available on request. — Article 5(13)
- [ ] **Label and access information,** including the Basic UDI-DI or UDI-DI and how to obtain paper. — Article 6
- [ ] **An internet address that stays stable** and directly accessible for the whole of the retention period. — Article 7(2)(e)
- [ ] **The address registered in the UDI database,** from the date device registration applies. — Article 7(3)

Three points that sit outside the gates

ARTICLES 3(3), 6(5), 9

Software. Where software is covered by the MDR, the manufacturer may provide the instructions through the software itself rather than on paper (Article 3(3)). Gates 3 and 4 fall away. Gates 5 and 6 do not, because Articles 4 and 5 apply to devices referred to in Article 3, paragraphs 1 and 3.

The electronic form itself. The instructions have to be available in full as text, which may contain symbols and graphics. Video and audio may be provided in addition to the text, and not in place of it (Article 6(5)).

Electronic instructions supplied alongside paper. The gates above do not apply where a complete printed leaflet is still supplied. Electronic instructions provided in addition to paper have to be consistent with the content of the paper version (Article 9).

Where these gates come from

Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 as regards electronic instructions for use of medical devices. OJ L 448, 15.12.2021, p. 32.

Commission Implementing Regulation (EU) 2025/1234 of 25 June 2025 amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form. OJ L, 26.6.2025. In force 16 July 2025. Recital 3 covers devices under the transitional provisions of Article 120 of the MDR.

Regulation (EU) 2017/745 on medical devices. Article 1(4); Annex I, Chapter III, 23.1, points (d) and (f). OJ L 117, 5.5.2017, p. 1.

Regulation (EU) 2017/746 on in vitro diagnostic medical devices. Annex I, Chapter III, 20.1(f). OJ L 117, 5.5.2017, p. 176.

This worksheet was compiled by Ydntfy, which runs electronic instructions for use for medical device and IVD manufacturers. The gates are set out with the article behind each one at ydntfy.com/en/resources/eifu-eligibility/.