eIFU COMPLIANCE CHECKLIST

The eIFU conditions, and the evidence behind each one

Twenty-five conditions drawn from Articles 4 to 7 of Commission Implementing Regulation (EU) 2021/2226, as amended by Regulation (EU) 2025/1234. Each line is either answerable with a document reference or it is not.

Article 8, which required a notified body to review these conditions, was deleted with effect from 16 July 2025 as redundant with conformity assessment under the MDR. The conditions that remain were not relaxed.

HOW TO USE IT	SCOPE	VERSION
Run it per device family. The lines you cannot point at a document for are the work.	Medical devices under the MDR. IVDs follow Annex I, 20.1(f) of the IVDR.	1.0, 18 August 2026. Law as it stood on that date.

Risk assessment ARTICLE 4

- [ ] **Risk assessment on file**, covering at least the eleven elements listed at Article 4(1), with a process to update it from post-market experience. — Article 4(1), 4(2)

Conditions on the instructions ARTICLE 5

- [ ] **Safety demonstration** recorded as a conclusion: the electronic form maintains or improves the level of safety obtained on paper. — Article 5(1)
- [ ] **Coverage of every Member State** where the device is made available or put into service, or a justification in the risk assessment. — Article 5(2)
- [ ] **Paper-on-request procedure** naming the intake route, the internal owner, who prints, and the committed period. Outer limit 7 calendar days. — Article 5(3)
- [ ] **Request records** showing the committed period was met in practice, at no additional cost to the user. — Article 5(3)
- [ ] **Emergency information** on the device or a leaflet, with start-up information where the device has a built-in display. — Article 5(4)
- [ ] **Verification and validation records** for the proper design and functioning of the electronic instructions. The scope of this condition is unsettled; record what you checked and why. — Article 5(5)
- [ ] **Built-in display assessment**, where the device has one, showing that displaying the instructions does not impede safe use. — Article 5(6)
- [ ] **Hardware and software requirements** published in the catalogue or other appropriate device information support. — Article 5(7)
- [ ] **Revision procedure** covering how a revision is signalled, and how each user is informed where it was necessary for safety reasons. — Article 5(8)

- [ ] **Retention period determined** per device family, with the reasoning. 10 years for devices with a defined expiry date, implantable devices excepted, and at least 2 years beyond the end of that expiry date. 15 years for implantable devices and for devices without a defined expiry date. — Article 5(9), 5(10)
- [ ] **Language matrix** mapping each market to the official EU language that Member State determines. — Article 5(11)
- [ ] **Version history published** with publication dates for the retention period, and a route for supplying obsolete versions on request. — Article 5(13)

Label and access information ARTICLE 6

- [ ] **Label artwork** stating that the instructions are supplied electronically, in the location required for the device type. — Article 6(1)
- [ ] **Access information** on the unit or sales packaging, and on the device itself for fixed installed devices; in a paper document supplied with each device where that is not practicable. — Article 6(2)
- [ ] **Access information complete** on all four points: what is needed to view, the Basic UDI-DI and/or UDI-DI, manufacturer contact details, and how and within what time paper can be requested — the period set in the risk assessment, capped at 7 calendar days. — Article 6(3)
- [ ] **Instructions available entirely as text**, which may contain symbols and graphics. Video or audio may be added to the text, never substituted for it. — Article 6(5)

The website ARTICLE 7

- [ ] **Website access** for instructions that also travel on an electronic storage medium or a built-in display. — Article 7(1)
- [ ] **Commonly used format**, readable with freely available software. — Article 7(2)(a)
- [ ] **Access control and tamper protection**, with the performance of those safeguards assessed under Article 4(1)(e). — Article 7(2)(b)
- [ ] **Availability records** showing that server downtime and display errors are reduced as far as possible. — Article 7(2)(c)
- [ ] **GDPR position documented** for the website carrying the instructions. — Article 7(2)(d)
- [ ] **Written commitment that the internet address is stable** and directly accessible for the whole of the 10- or 15-year retention period. — Article 7(2)(e)
- [ ] **eIFU address registered in the UDI database**, from the date device registration applies. Annex VI, Part B, point 22 of the MDR marks the field optional; this provision does not. — Article 7(3)

Technical documentation MDR ANNEX II

- [ ] **Labels and instructions for use filed** in the languages accepted in the Member States where the device is envisaged to be sold, so a reviewer finds the evidence above without asking. — MDR Annex II, 2

Where these conditions 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.

Regulation (EU) 2017/745 on medical devices. Annex I, Chapter III, 23.1(f); Annex II, point 2; Article 52; Annex VI, Part B, point 22. OJ L 117, 5.5.2017, p. 1.

This checklist was compiled by Ydntfy, which runs electronic instructions for use for medical device and IVD manufacturers. The conditions are set out article by article, with what demonstrates each one, at ydntfy.com/en/resources/eifu-notified-body-website-checklist/.