

IVDR: In Vitro Diagnostic Medical Devices Regulation (Regulation (EU) 2017/746), explained

The In Vitro Diagnostic Medical Devices Regulation governs in vitro diagnostic devices on the EU market, from classification in classes A to D to notified-body assessment, CE marking and Eudamed, for manufacturers, importers and distributors. It has applied since 26 May 2022; directive-covered devices may stay on the market until 31 December 2027, 2028 or 2029 under Regulation (EU) 2024/1860.

Reviewed 24 September 2026 by Conphora compliance team · Next review 12 March 2027 · Not legal advice

Key facts

Reference	Regulation (EU) 2017/746	Act type	Regulation
In force	25 May 2017	Applies from	26 May 2022
Amended by	Regulation (EU) 2022/112, Commission Delegated Regulation (EU) 2023/503, Regulation (EU) 2023/607, Regulation (EU) 2024/1860	Enforced by	National competent authorities for in vitro diagnostic medical devices carry out the market surveillance under Chapter VII of the regulation; in Denmark that is Lægemiddelstyrelsen (the Danish Medicines Agency), which supervises manufacturers and the other economic operators, receives incident and supply-interruption reports, verifies the Eudamed actor registrations that lead to a single registration number and registers Danish distributors and specialist retailers of IVDs, under lov om medicinsk udstyr, lovbekendtgørelse nr. 682 af 29. maj 2023, as amended by lov nr. 1759 of 29 December 2025, and bekendtgørelse nr. 1731 af 8. december 2025 om medicinsk udstyr m.v. (in force 1 January 2026, repealing bekendtgørelse nr. 837 af 20. juni 2023 om medicinsk udstyr m.v., the previous executive order on medical devices, under its § 21, stk. 2).

Key dates

5 April 2017	Regulation (EU) 2017/746 adopted by the European Parliament and the Council in Strasbourg; published in OJ L 117 on 5 May 2017	title and signature block after Art. 113
25 May 2017	Entry into force, the twentieth day after publication in the Official Journal	Art. 113(1)
26 November 2017	Articles 31 to 46 on notified bodies and Article 96 on competent authorities apply, so that bodies could be designated under the regulation before the date of application	Art. 113(3), point (b)
26 May 2018	Article 97 on cooperation between Member States applies	Art. 113(3), point (c)
26 May 2019	GS1, HIBCC and ICCBBA are deemed designated UDI issuing entities until the Commission designates entities under Article 24(2)	Art. 110(10) and Art. 113(3), point (h)
25 November 2020	Article 100 on the EU reference laboratories for class D devices applies	Art. 113(3), point (d)
28 January 2022	Regulation (EU) 2022/112 in force on the day of publication: transitional periods staggered by risk class for devices that need a notified body for the first time, sell-off dates extended, and the Article 5(5) conditions for in-house devices deferred to 26 May 2024 and 26 May 2028	Art. 1 and Art. 2
26 May 2022	The regulation applies; Directive 98/79/EC is repealed subject to the transitional provisions and notifications of notified	Art. 110(1), Art. 112 and Art. 113(2)

bodies under it become
void

11 March 2023	Delegated Regulation (EU) 2023/503 in force: complete re-assessment of notified bodies every 5 years instead of 3 years after notification and every 4 years thereafter	Art. 1 and Art. 2
20 March 2023	Regulation (EU) 2023/607 in force on the day of publication: devices lawfully placed on the market under Directive 98/79/EC or under the transitional provisions may continue to be made available without a sell-off deadline	Art. 2 and Art. 3
26 May 2023	UDI carrier required on the label and all higher packaging levels of class D devices	Art. 24(4) and Art. 113(3), point (e)
26 May 2024	Article 5(5), points (b), (c) and (e) to (i), apply to in- house devices: quality management system, EN ISO 15189 laboratory, information to the competent authority, public declaration, class D documentation, manufacture to the documentation and review of clinical experience	Art. 5(5) and Art. 113(3), point (i)
9 July 2024	Regulation (EU) 2024/1860 in force on the day of publication: transition extended to 31 December 2027, 2028 and 2029 by class with conditions, gradual roll- out of Eudamed module by module, new Article 10a on supply interruptions, Article 5(5), point (d), deferred to 31 December 2030	Art. 2 and Art. 3

10 January 2025	Article 10a applies: manufacturers must give at least 6 months' notice of an anticipated interruption or discontinuation of supply that could cause serious harm	Art. 2, point (1), and Art. 3
26 May 2025	UDI carrier required on the labels of class B and class C devices; deadline for legacy-device manufacturers to have a quality management system under Article 10(8), and for class D and certificate devices to have lodged a formal application with a notified body	Art. 113(3), point (e), and Art. 110(3c), points (d) and (e)(i)
27 May 2025	Certificates issued under Annex VI to Directive 98/79/EC (EC verification) become void at the latest	Art. 110(2), first subparagraph
26 September 2025	Deadline for the written agreement between the manufacturer and a notified body for class D and certificate legacy devices; from this date that notified body is responsible for their surveillance	Art. 110(3c), point (f)(i), and Art. 110(3e)
27 November 2025	Commission Decision (EU) 2025/2371 published: the Eudamed modules for actors, UDI and devices, notified bodies and certificates, and market surveillance are confirmed functional, starting the 6-month clock of Article 113(3), point (f)	Art. 1 and Art. 2; Art. 113(3), point (f)
26 May 2026	Deadline for class C legacy devices to have a formal application lodged with a notified body	Art. 110(3c), point (e)(ii)
28 May 2026	Mandatory use of the first four Eudamed modules	Art. 113(3), point (f)

(actor registration, UDI and device registration, notified bodies and certificates, market surveillance); manufacturers, authorised representatives and importers register in Eudamed instead of national databases — the Commission gives 28 May 2026; Article 113(3), point (f), counts six months from the publication of the notice on 27 November 2025, so plan for 27 May 2026

26 September 2026	Deadline for the written agreement between the manufacturer and a notified body for class C legacy devices	Art. 110(3c), point (f)(ii)
28 November 2026	Deadline (6 months after the Eudamed date of 28 May 2026) for manufacturers to have entered in Eudamed the Article 26 information on devices placed on the market from 28 May 2026, including legacy devices under Article 110(3), (3a) and (3b) (27 November 2026 on a strict count from the notice)	Art. 113(3), point (fa); Art. 2
26 May 2027	UDI carrier required on the labels of class A devices; deadline for class B and sterile class A legacy devices to have a formal application lodged with a notified body	Art. 113(3), point (e), and Art. 110(3c), point (e)(iii)
27 May 2027	Deadline for the Commission's evaluation report on the application of the regulation, with special attention to UDI storage and traceability and to Article 4	Art. 111

28 May 2027	Deadline (12 months after the Eudamed date) for notified bodies to have entered their certificates in Eudamed; the duties to upload the summary of safety and performance and to notify certificates follow the certificate entry (27 May 2027 on a strict count from the notice)	Art. 113(3), points (fb) and (fc)
26 September 2027	Deadline for the written agreement between the manufacturer and a notified body for class B and sterile class A legacy devices	Art. 110(3c), point (f)(iii)
31 December 2027	End of the transitional period for class D legacy devices and for every device covered by a directive certificate; directive certificates issued from 25 May 2017 that were valid on 26 May 2022 expire at the latest	Art. 110(2), second subparagraph, Art. 110(3a) and Art. 110(3b), point (a)
31 December 2028	End of the transitional period for class C legacy devices	Art. 110(3b), point (b)
31 December 2029	End of the transitional period for class B legacy devices and class A devices placed on the market in sterile condition	Art. 110(3b), point (c)
31 December 2030	Article 5(5), point (d), applies: health institutions must document that no equivalent CE-marked device on the market meets the target patient group's needs before making an in-house device	Art. 113(3), point (j)

Obligations by role

Manufacturer (including own-brand sellers and persons who change or modify a device)

- Design and manufacture the device to the general safety and performance requirements of Annex I for its intended purpose, run a documented risk management system, and demonstrate conformity through a performance evaluation under Article 56 and Annex XIII that establishes scientific validity, analytical performance and clinical performance, with clinical performance studies unless reliance on other data is justified, and a post-market performance follow-up plan; the performance evaluation report is part of the technical documentation and is updated at least annually for class C and D devices.

Art. 5(2) and (3), Art. 10(1) to (3) and Art. 56

- Design and manufacture the device so that it meets the general safety and performance requirements of Annex I that apply to it, taking its intended purpose into account. Art. 5(2) and Art. 10(1)
- Establish, document, implement and maintain a risk management system for the device, as a continuous process throughout its lifecycle. Art. 10(2)
- Conduct a performance evaluation under Article 56 and Annex XIII that establishes scientific validity, analytical performance and clinical performance, with a post-market performance follow-up plan; keep the report in the technical documentation and update it at least annually for class C and D devices.

Art. 5(3), Art. 10(3) and Art. 56

- Classify the device into class A, B, C or D using the seven rules and ten implementing rules of Annex VIII and run the matching conformity assessment before placing it on the market: Annex IX Chapters I, II and III (or Annex X with Annex XI) with technical-documentation assessment of every device, EU reference laboratory testing and, where no common specification exists, an expert-panel consultation for class D; Annex IX Chapters I and III with assessment of at least one representative device per generic device group (or Annex X with XI) for class C; Annex IX Chapters I and III with one representative device per category for class B; the EU declaration of conformity on your own technical documentation for class A, with a notified body for the sterility aspects only where the device is sterile; plus Section 5.1 of Annex IX for self-testing and near-patient tests and the medicinal-product consultation of Section 5.2 for companion diagnostics. Art. 47(1) and Art. 48(1) to (10)
- Classify the device into class A, B, C or D using the seven classification rules and the implementing rules of Annex VIII. Art. 47(1) and Annex VIII
- Before placing the device on the market, run the conformity assessment procedure of Article 48 for its class: Annex IX or Annex X with XI through a notified body for classes B, C and D, and self-declaration for class A, with a notified body only for sterile aspects. Art. 48(1) to (10)
- Draw up and keep up to date the technical documentation of Annexes II and III, draw up the EU declaration of conformity with the Annex IV content and the Basic UDI-DI, translated into the languages the Member States require, affix the CE marking followed by the notified body's number where applicable, and keep the documentation, declaration and certificates available to authorities for at least 10 years after the last device covered by the declaration was placed on the market; notified-body certificates run for at most 5 years and are renewable.

Art. 10(4), (5) and (7), Art. 17, Art. 18, Art. 24(6) and Art. 51(2)

- Draw up and keep up to date the technical documentation of Annexes II and III, including the post-market surveillance documentation. Art. 10(4)
- Draw up the EU declaration of conformity with the Annex IV content and the Basic UDI-DI, translated into the languages the Member States where the device is made available require, and keep it up to date.

Art. 10(5) and Art. 17

- Affix the CE marking to the device, followed by the identification number of the notified body where a notified body was involved in the conformity assessment. Art. 10(5) and Art. 18

- Keep the technical documentation, the EU declaration of conformity and any certificates available to the competent authorities for at least 10 years after the last device covered by the declaration was placed on the market. Art. 10(7)
- Operate a quality management system proportionate to the risk class and type of device that covers the thirteen elements of Article 10(8), from regulatory strategy, risk management and performance evaluation to UDI verification, post-market surveillance, vigilance and corrective actions, keep series production in conformity, and have at least one person responsible for regulatory compliance with the Article 15 qualifications in the organisation, or permanently at your disposal if you are a micro or small enterprise. Art. 10(8) and Art. 15(1) to (3)
- Operate and keep up to date a quality management system, proportionate to the risk class and type of device, that covers the elements of Article 10(8) and keeps series production in conformity. Art. 10(8)
- Have within your organisation at least one person responsible for regulatory compliance with the Article 15 qualifications or, as a micro or small enterprise, have such a person permanently and continuously at your disposal. Art. 15(1) to (3)
- Assign a UDI (UDI-DI and UDI-PI) from a designated issuing entity to every device other than devices for performance study and to all higher packaging levels, place the UDI carrier on the label and packaging within the class-based dates of Article 113(3), point (e) (class D since 26 May 2023, classes B and C since 26 May 2025, class A from 26 May 2027), keep a list of all UDIs in the technical documentation, and assign a Basic UDI-DI and submit the Annex VI core data to the UDI database before placing the device on the market, and before applying to a notified body where one is involved.
Art. 24(1), (3), (4) and (7), Art. 26(1) and (2) and Art. 113(3), point (e)
- Assign a UDI (UDI-DI and UDI-PI) from a designated issuing entity to each device and higher packaging level, place the UDI carrier on the label and packaging by the class-based dates of Article 113(3)(e), and keep the list of UDIs in the technical documentation. Art. 24(1), (3), (4) and (7) and Art. 113(3), point (e)
- Assign a Basic UDI-DI and submit the Annex VI core data to the UDI database before placing the device on the market, and before applying to a notified body where one is involved. Art. 26(1) and (2)
- Register as an actor in Eudamed to obtain a single registration number before placing a device on the market (and before applying to a notified body), update the data within one week of any change, confirm it after one year and every second year, and register each device in Eudamed: the registration modules are mandatory from 28 May 2026 and devices placed on the market from that date must be entered no later than 28 November 2026. Art. 26(3), Art. 28 and Art. 113(3), points (f) and (fa); Art. 1
- Register as an actor in Eudamed to obtain a single registration number before placing a device on the market and before applying to a notified body. Art. 28; Art. 1
- Update your Eudamed actor data within one week of any change, and confirm its accuracy one year after registration and every second year thereafter. Art. 28; Art. 1
- Register each device in Eudamed: the registration modules are mandatory from 28 May 2026, and devices placed on the market from that date must be entered no later than 28 November 2026.
Art. 26(3) and Art. 113(3), points (f) and (fa); Art. 1
- Supply the label and instructions for use with the Annex I, Section 20 information in the official language(s) of the Member State where the device reaches the user or patient, with indelible and legible label particulars and, for self-testing and near-patient tests, information that is easily understandable; for class C and D devices draw up a summary of safety and performance, validated by the notified body and published in Eudamed, and state on the label or instructions where it is available; and do not use claims, names or pictures that mislead on intended purpose, safety or performance.

Art. 7, Art. 10(10) and Art. 29

- Supply the label and instructions for use with the Annex I, Section 20 information in the official language(s) of the Member State where the device reaches the user or patient, indelible and legible, and easily understandable for self-testing and near-patient tests. Art. 10(10)
- For class C and D devices, draw up a summary of safety and performance, have it validated by the notified body for publication in Eudamed, and state on the label or instructions where it is available.

Art. 29

- Do not use text, names, trademarks, pictures or signs in labelling, instructions, making available or advertising that mislead the user or patient on the device's intended purpose, safety or performance.

Art. 7

- Plan, run and update a post-market surveillance system with a plan in the technical documentation, and produce a post-market surveillance report for class A and B devices or a periodic safety update report for class C and D devices updated at least annually, submitted through the electronic system to the notified body for class D devices and made available to the notified body for class C devices.

Art. 10(9) and Art. 78 to 81

- Plan, run and keep up to date a post-market surveillance system proportionate to the risk class, based on a post-market surveillance plan that is part of the technical documentation. Art. 10(9), Art. 78 and Art. 79
- Produce a post-market surveillance report for class A and B devices, or for class C and D devices a periodic safety update report updated at least annually, submitted through Eudamed to the notified body for class D and made available to it for class C. Art. 80 and Art. 81
- Report serious incidents through the vigilance system immediately and no later than 15 days after becoming aware, 2 days for a serious public health threat and 10 days for a death or unanticipated serious deterioration in health; report field safety corrective actions in advance except in urgent cases, issue field safety notices to users, investigate incidents and provide a final report, and submit trend reports for statistically significant increases in non-serious incidents or in expected erroneous results.

Art. 10(12) and Art. 82 to 84

- Report each serious incident to the competent authority immediately and no later than 15 days after becoming aware, 2 days for a serious public health threat and 10 days for a death or unanticipated serious deterioration in health; investigate it and provide a final report.

Art. 10(12), Art. 82(1)(a) and (3) to (5) and Art. 84

- Report each field safety corrective action to the competent authorities before undertaking it, except in urgent cases, and bring it to the users' attention without delay through a field safety notice.

Art. 82(1)(b) and Art. 84(8)

- Report any statistically significant increase in the frequency or severity of incidents that are not serious incidents, or in expected erroneous results, that could significantly affect the benefit-risk analysis. Art. 83
- Take immediate corrective action, withdrawal or recall where a device you placed on the market does not conform, inform distributors, the authorised representative and importers, and where the device presents a serious risk inform the competent authorities and the notified body; on request provide all conformity information in the language the Member State determines, samples or access, and cooperate on risk-mitigation measures; keep proportionate financial coverage for product liability.

Art. 10(11), (13) and (15)

- Where a device you placed on the market does not conform, immediately take corrective action, withdraw or recall it, inform distributors, the authorised representative and importers, and where it presents a serious risk inform the competent authorities and the notified body. Art. 10(11)

- On a competent authority's request, provide all information and documentation demonstrating conformity in the language the Member State determines, provide samples or access to the device, and cooperate on measures to eliminate or mitigate risks. Art. 10(13)
- Have measures in place to provide sufficient financial coverage for your potential liability for defective devices, proportionate to the risk class, type of device and size of the enterprise. Art. 10(15)
- Give the competent authority of your or your authorised representative's Member State and your direct customers, health institutions and healthcare professionals at least 6 months' notice of an anticipated interruption or discontinuation of supply of a device that could foreseeably cause serious harm to patients or public health, stating the reasons; the duty applies since 10 January 2025 and covers legacy devices, and in Denmark the notice goes to Lægemiddelstyrelsen. Art. 10a and Art. 110(11); Art. 3
- If you are established outside the Union, designate a sole authorised representative under a written mandate covering at least the Article 11(3) tasks and keep the documentation permanently available to it; and if you offer devices or a diagnostic service to persons in the Union online, comply with the regulation and provide a copy of the EU declaration of conformity on request.

Art. 6, Art. 10(7), third subparagraph, and Art. 11(1)

- If you are established outside the Union, designate a sole authorised representative under a written mandate covering at least the Article 11(3) tasks, and keep the technical documentation permanently available to it. Art. 10(7), third subparagraph, and Art. 11(1)
- If you offer devices or a diagnostic service to persons in the Union online or by other distance means, make sure the device complies with this regulation and provide a copy of the EU declaration of conformity on an authority's request. Art. 6

Authorised representative

- Accept the written mandate, which is effective at least for all devices of the same generic device group, perform the tasks it specifies and provide a copy to the competent authority on request; the mandate cannot delegate the manufacturer's core duties in Article 10(1), (2), (3), (4), (5), (6), (8), (9), (10) and (11). Art. 11(2) to (4)
- Verify that the EU declaration of conformity and technical documentation have been drawn up and that the applicable conformity assessment was carried out, and keep a copy of the technical documentation, the declaration and any certificate at the disposal of the competent authorities for 10 years after the last device was placed on the market. Art. 11(3), points (a) and (b), and Art. 10(7)
- Verify that the EU declaration of conformity and the technical documentation have been drawn up and that the manufacturer has carried out the applicable conformity assessment procedure. Art. 11(3), point (a)
- Keep a copy of the technical documentation, the EU declaration of conformity and any certificate at the disposal of the competent authorities for 10 years after the last device covered by the declaration was placed on the market. Art. 11(3), point (b), and Art. 10(7)
- Register in Eudamed to obtain your own single registration number, verify that the manufacturer has met its device registration obligations, and keep your actor data updated and confirmed.
Art. 11(3), point (c), and Art. 28
- Register in Eudamed to obtain your own single registration number, and keep your actor data updated and confirmed. Art. 28
- Verify that the manufacturer has complied with its registration obligations for the device and for itself.
Art. 11(3), point (c)
- On request, provide the competent authority with all information and documentation demonstrating conformity in the language it determines, forward requests for samples or access to the manufacturer and verify that the authority receives them, and cooperate on preventive or corrective action.
Art. 11(3), points (d) to (f)
- Immediately inform the manufacturer of complaints and reports from healthcare professionals, patients and users about suspected incidents, and terminate the mandate if the manufacturer acts contrary to its obligations, informing the competent authority and the notified body of the termination and its reasons.
Art. 11(3), points (g) and (h), and Art. 11(6)
- Immediately inform the manufacturer of complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device covered by your mandate. Art. 11(3), point (g)
- Terminate the mandate if the manufacturer acts contrary to its obligations under this regulation, and inform the competent authority of your Member State and, where applicable, the notified body of the termination and its reasons. Art. 11(3), point (h), and Art. 11(6)
- Have permanently and continuously at your disposal at least one person responsible for regulatory compliance with a relevant degree plus one year's experience or four years' experience in regulatory affairs or quality management for in vitro diagnostic medical devices. Art. 15(6)
- Expect joint and several liability with the manufacturer for defective devices where a non-EU manufacturer has not complied with Article 10, and define a change of authorised representative in a written agreement covering the dates, documents and the forwarding of complaints. Art. 11(5) and Art. 12
- Where the non-EU manufacturer has not complied with its Article 10 obligations, you are legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer. Art. 11(5)
- On a change of authorised representative, define the change in an agreement between the manufacturer, the outgoing and the incoming representative covering the end and start dates of the

mandates, the transfer of documents and the forwarding of complaints and incident reports. Art. 12

Importer

- Place only conforming devices on the Union market and, before doing so, verify that the device is CE-marked and the EU declaration of conformity drawn up, that a manufacturer is identified and an authorised representative designated, that the device is labelled and accompanied by instructions for use as required, and that a UDI has been assigned where applicable; hold non-conforming devices back and inform the manufacturer and its representative, and the competent authority where the device presents a serious risk or is falsified. Art. 13(1) and (2)
- Indicate your name, registered trade name or trade mark, registered place of business and contact address on the device, its packaging or an accompanying document without obscuring the manufacturer's label; if you translate the information or repackage the device, follow the Article 16(2) to (4) conditions, including a notified-body certificate for your quality management system and 28 days' notice to the manufacturer and the competent authority. Art. 13(3) and Art. 16(2) to (4)
- Indicate your name, registered trade name or registered trade mark, registered place of business and contact address on the device, its packaging or an accompanying document, without obscuring the manufacturer's label. Art. 13(3)
- If you translate the manufacturer's information or repackage the device, meet the Article 16(2) to (4) conditions: a quality management system certified by a notified body for those activities, and 28 days' notice to the manufacturer and the competent authority before making the device available.
Art. 16(2) to (4)
- Verify that the device is registered in Eudamed, add your details to the registration, register yourself as an actor to obtain a single registration number, and within two weeks of placing a device on the market check that the manufacturer or authorised representative has entered the actor information; in Denmark, Lægemiddelstyrelsen verifies your actor data before Eudamed issues the number and asks importers to state the risk classes of the devices they import. Art. 13(4), Art. 27(3) and Art. 28
- Verify that the device is registered in Eudamed and add your details to the registration, and within two weeks of placing it on the market check that the manufacturer or authorised representative has entered the actor information. Art. 13(4) and Art. 27(3)
- Register as an actor in Eudamed to obtain a single registration number; in Denmark, Lægemiddelstyrelsen verifies your actor data before the number is issued and asks you to state the risk classes of the devices you import. Art. 28
- Keep storage and transport conditions from jeopardising compliance with Annex I and follow the manufacturer's conditions, and keep a register of complaints, non-conforming devices, recalls and withdrawals, sharing the information the manufacturer, authorised representative and distributors need to investigate complaints. Art. 13(5) and (6)
- While a device is under your responsibility, keep storage and transport conditions from jeopardising its compliance with Annex I and follow the conditions set by the manufacturer. Art. 13(5)
- Keep a register of complaints, non-conforming devices, recalls and withdrawals, and give the manufacturer, authorised representative and distributors the information they need to investigate complaints. Art. 13(6)
- Where a device you placed on the market does not conform, immediately inform the manufacturer and its representative and cooperate on corrective action, withdrawal or recall; where it presents a serious risk also inform the competent authorities and the notified body; and forward complaints and suspected-incident reports from healthcare professionals, patients or users to the manufacturer and its representative immediately. Art. 13(7) and (8)

- Where a device you placed on the market does not conform, immediately inform the manufacturer and its authorised representative and cooperate on corrective action, withdrawal or recall; where it presents a serious risk, also inform the competent authorities and the notified body. Art. 13(7)
- Immediately forward complaints and reports of suspected incidents from healthcare professionals, patients or users to the manufacturer and its authorised representative. Art. 13(8)
- Keep a copy of the EU declaration of conformity and any certificate for the Article 10(7) period of 10 years, cooperate with competent authorities on risk-elimination measures, provide free samples or access to the device on request, and be able to identify to the authority every operator you supplied or were supplied by and every health institution or professional you supplied directly.

Art. 13(9) and (10) and Art. 22

- Keep a copy of the EU declaration of conformity and any certificate for the Article 10(7) period of at least 10 years after the last device was placed on the market. Art. 13(9)
- Cooperate with the competent authorities, at their request, on measures to eliminate or mitigate risks, and provide free samples of the device or, where impracticable, access to it. Art. 13(10)
- Be able to identify to the competent authority, for the Article 10(7) period, every economic operator you supplied or were supplied by and every health institution or healthcare professional you supplied directly. Art. 22
- If you market a device under your own name or trade mark, change its intended purpose or modify it in a way that may affect compliance, you assume the manufacturer's obligations, unless the manufacturer is identified on the label and contractually remains responsible. Art. 16(1)

Distributor (wholesaler, pharmacy, laboratory supplier, retailer)

- Act with due care and, before making a device available, verify (by representative sampling where allowed) that it is CE-marked with an EU declaration of conformity, accompanied by the manufacturer's label and instructions in the required language, that the importer has added its identification, and that a UDI has been assigned where applicable; hold non-conforming devices back, inform the manufacturer, its representative and the importer, and inform the competent authority where the device presents a serious risk or is falsified. Art. 14(1) and (2)
- Keep storage and transport conditions in line with the manufacturer's conditions while the device is under your responsibility, which for reagents and controls typically means the cold chain stated on the label. Art. 14(3)
- Where a device you made available does not conform, immediately inform the manufacturer, its representative and the importer and cooperate on corrective action, withdrawal or recall; where it presents a serious risk, immediately inform the competent authorities of the Member States concerned. Art. 14(4)
- Forward complaints and suspected-incident reports from healthcare professionals, patients or users to the manufacturer, its representative and the importer immediately, and keep a register of complaints, non-conforming devices, recalls and withdrawals. Art. 14(5)
- Immediately forward complaints and reports of suspected incidents from healthcare professionals, patients or users to the manufacturer and, where applicable, its authorised representative and the importer. Art. 14(5)
- Keep a register of complaints, non-conforming devices, recalls and withdrawals, and keep the manufacturer, authorised representative and importer informed of that monitoring. Art. 14(5)
- On request, provide the competent authority with the information and documentation at your disposal demonstrating conformity, cooperate on risk-elimination measures, provide free samples or access to the device, and be able to identify every operator, health institution or professional you supplied directly for 10 years. Art. 14(6) and Art. 22
- On a competent authority's request, provide the information and documentation at your disposal demonstrating conformity, cooperate on measures to eliminate risks, and provide free samples of the device or access to it. Art. 14(6)
- Be able to identify to the competent authority, for 10 years, every economic operator you supplied or were supplied by and every health institution or healthcare professional you supplied directly. Art. 22
- If you sell under your own name or trade mark, change the intended purpose or modify the device, you take on the manufacturer's obligations; if you translate the information or repackage the device, you need a quality management system certified by a notified body and must notify the manufacturer and the competent authority 28 days before making the relabelled or repackaged device available. Art. 16(1) to (4)
- If you make a device available under your own name or trade mark, change its intended purpose or modify it in a way that may affect compliance, you take on the manufacturer's obligations. Art. 16(1)
- If you translate the manufacturer's information or repackage the device, meet the Article 16(2) to (4) conditions: a quality management system certified by a notified body for those activities, and 28 days' notice to the manufacturer and the competent authority before making the device available. Art. 16(2) to (4)
- Where national law requires it, register as a distributor: in Denmark, distributors and specialist retailers of IVDs established in Denmark register with Lægemiddelstyrelsen from 28 May 2026 through its own

database, which stays a national registration outside Eudamed and carries a registration fee and an annual fee under bekendtgørelse nr. 1733 af 8. december 2025 om gebyrer for importører og distributører af medicinsk udstyr m.v. (in force 1 January 2026; registration fee DKK 1 238 and an annual supervision fee scaled by the number of employees). Art. 27(2)

Penalties

Member States lay down the rules on penalties for infringements of the regulation and take all measures necessary to ensure that they are implemented; the penalties must be effective, proportionate and dissuasive and were notified to the Commission by 25 February 2022. Competent authorities check devices through documentation reviews, physical or laboratory checks and announced or unannounced inspections of economic operators, suppliers and subcontractors, may require documentation, information and free samples, and may confiscate, destroy or render inoperable devices that present an unacceptable risk or are falsified. Where a device presents an unacceptable risk they require corrective action, restriction, specific conditions, withdrawal or recall within a set period and, if the operator fails to act, prohibit or restrict the making available, withdraw or recall the device and notify the Commission and the other Member States through the market-surveillance module of Eudamed; other non-compliance must be ended within a set period, otherwise the same measures follow; a Member State may also take preventive health-protection measures against a category of devices. A manufacturer that fails to cooperate or provides incomplete information can see its device prohibited, restricted, withdrawn or recalled until it complies. In Denmark, Lægemiddelstyrelsen (the Danish Medicines Agency) supervises manufacturers and the other operators and applies lov om medicinsk udstyr, lov bekendtgørelse nr. 682 af 29. maj 2023, as amended by lov nr. 1759 of 29 December 2025, and bekendtgørelse nr. 1731 af 8. december 2025 om medicinsk udstyr m.v. (in force 1 January 2026, repealing bekendtgørelse nr. 837 af 20. juni 2023 om medicinsk udstyr m.v., the previous executive order on medical devices, under its § 21, stk. 2), with fees under bekendtgørelse nr. 839 af 20. juni 2023 om gebyrer for medicinsk udstyr m.v., som ændret ved bekendtgørelse af 6. december 2024 og bekendtgørelse nr. 1739 af 8. december 2025, and bekendtgørelse nr. 1733 af 8. december 2025 om gebyrer for importører og distributører af medicinsk udstyr m.v. (in force 1 January 2026; registration fee DKK 1 238 and an annual supervision fee scaled by the number of employees); the Danish product act (lov om produkter og markedsovervågning, consolidated as LBK nr. 22 of 8 January 2026) does not cover medical devices or in vitro diagnostics — neither Regulation (EU) 2017/745 nor Regulation (EU) 2017/746 appears in it — so the Danish framework for IVDs is the act on medical devices alone. Breaches of Regulation (EU) 2017/746, and failures to comply with an order, a prohibition or a duty to provide information under it, are punished in Denmark with a fine or imprisonment of up to 1 year and 6 months under section 6(2) of the Danish act on medical devices, executive orders made under the act may set fines of their own (section 6(3)) — executive order nr. 1731 of 8 December 2025 does so in its section 20 for, among other things, the incident-reporting and registration duties of its sections 8 to 15 — and companies can be held liable under chapter 5 of the criminal code (section 6(4)).

Art. 106, Art. 10(13), Art. 88 to 94; § 6, stk. 2, 3 og 4; § 20; § 2

Checklist

- 1. Confirm the product is an IVD under Article 2, point (2): intended by you for in vitro examination of human specimens to provide one of the six kinds of information listed there; check that no Article 1(3) exclusion (general laboratory or research-use-only product, invasive sampling product, certified reference material, EQA material) applies and that a device with an integral medical device is handled under the MDR (Article 1(4)).
- 2. Decide your role for each device: manufacturer, authorised representative, importer or distributor, remembering that own-brand sales, changing the intended purpose or modifying a device make you the manufacturer (Article 16); a health institution making its own tests checks the nine conditions of Article 5(5).
- 3. Classify the device with the seven rules of Annex VIII, applying the implementing rules on accessories, software, calibrators and controls, and record the rationale; the class sets the conformity route, the PSUR cycle and the UDI label date (Article 47, Article 113(3), point (e)).
- 4. Choose and book the conformity assessment: a notified body under Annex IX, X or XI for classes B, C and D and for the sterility aspects of sterile class A devices, with EU reference laboratory testing for class D, Section 5.1 for self-tests and near-patient tests and the medicinal-product consultation for companion diagnostics; the EU declaration of conformity alone for other class A devices (Article 48).
- 5. Build the technical documentation of Annexes II and III with the risk management file, the performance evaluation plan and report covering scientific validity, analytical and clinical performance with a PMPF plan, the label and instructions in the Member State languages, and the post-market surveillance plan (Articles 10(4), 56, 79 and Annex XIII).
- 6. Set up the quality management system of Article 10(8) and name the person responsible for regulatory compliance (Article 15); micro and small enterprises may contract the person externally.
- 7. Register as an actor in Eudamed to get your single registration number, assign the Basic UDI-DI and UDIs, place the UDI carrier on labels and packaging, and register each device in Eudamed by 28 November 2026 for devices placed on the market from 28 May 2026 (Articles 24, 26, 28 and 113(3), points (f) and (fa)).
- 8. Draw up the EU declaration of conformity with the Annex IV content, affix the CE marking with the notified body number, and for class C and D devices prepare the summary of safety and performance for validation and publication in Eudamed (Articles 17, 18 and 29).
- 9. Run vigilance and surveillance: a procedure that reports serious incidents within 15, 10 or 2 days, field safety corrective actions and notices, trend reports including increases in expected erroneous results, the PMS report or annual PSUR, and a supply-interruption notice at least 6 months ahead (Articles 10a and 78 to 84).
- 10. For legacy devices, map every directive certificate and declaration against 31 December 2027, 2028 or 2029, evidence the Article 110(3c) conditions (QMS and class D application by 26 May 2025, class C application by 26 May 2026, class B and sterile class A application by 26 May 2027, written agreements by the following 26 September) and apply the IVDR post-market, vigilance and registration rules already now (Article 110(3a) to (3d)).

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