

MDR: Medical Devices Regulation (Regulation (EU) 2017/745), explained

The Medical Devices Regulation governs medical devices, their accessories and Annex XVI products on the EU market, from classification and notified-body assessment to CE marking, Eudamed and vigilance, for manufacturers, importers and distributors. It has applied since 26 May 2021; directive-certified devices may stay on the market until 31 December 2027 or 2028 under Regulation (EU) 2023/607.

Reviewed 24 September 2026 by Conphora compliance team · Next review 14 March 2027 · Not legal advice

Key facts

Reference	Regulation (EU) 2017/745	Act type	Regulation
In force	25 May 2017	Applies from	26 May 2021
Amended by	Regulation (EU) 2020/561, Commission Delegated Regulation (EU) 2023/502, Regulation (EU) 2023/607, Commission Delegated Regulation (EU) 2023/2197, Regulation (EU) 2024/568, Regulation (EU) 2024/1860, Commission Delegated Regulation (EU) 2025/1920, Regulation (EU) 2025/2457, Commission Delegated Regulation (EU) 2026/1359, Commission Delegated Regulation (EU) 2026/1451	Enforced by	National competent authorities for 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, handles incident reports, verifies the Eudamed actor registrations that lead to a single registration number and registers Danish distributors and specialist retailers, under the Danish act on medical devices (lovbekendtgørelse nr. 682 af 29. maj 2023, as amended by lov nr. 1759 af 29. december 2025), whose § 3 names Lægemiddelstyrelsen as the competent authority, bekendtgørelse nr. 1731 af 8. december 2025 om medicinsk udstyr m.v. (in force 1 January 2026) and the fee orders bekendtgørelse nr. 839 af 20. juni 2023 (as amended) and bekendtgørelse nr. 1733 af 8. december 2025.

Key dates

5 April 2017	Regulation (EU) 2017/745 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. 123
25 May 2017	Entry into force, the twentieth day after publication in the Official Journal	Art. 123(1)
26 November 2017	Articles 35 to 50 on notified bodies and Articles 101 and 103 on the Medical Device Coordination Group apply, so that bodies could be designated under the regulation before the date of application	Art. 123(3), points (a) and (b)
26 May 2019	GS1, HIBCC and ICCBBA are deemed designated UDI issuing entities until the Commission designates entities under Article 27(2)	Art. 120(12) and Art. 123(3), point (i)
24 April 2020	Regulation (EU) 2020/561 in force on the day of publication: the date of application is postponed by one year to 26 May 2021 because of COVID-19, and the Article 59 derogation procedure applies immediately	Art. 1, points (4), (6) and (8), and Art. 2
26 May 2021	The regulation applies; Directives 90/385/EEC and 93/42/EEC are repealed and notifications of notified bodies under them become void; the UDI carrier must appear on the labels of implantable and class III devices	Art. 120(1), Art. 122, Art. 123(2) and Art. 123(3), point (f)
27 May 2022	Certificates issued under Annex 4 to Directive 90/385/EEC or Annex IV to Directive 93/42/EEC (EC verification) become void at the latest	Art. 120(2), first subparagraph
11 March 2023	Delegated Regulation (EU) 2023/502 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: directive certificates still valid on 26 May 2021 remain valid until 31 December 2027 or 31 December 2028 depending on risk class, and the sell-off deadline of Article 120(4) is removed	Art. 1 and Art. 3
26 May 2023	UDI carrier required on the labels of class IIa and IIb devices, and directly on reusable implantable and class III	Art. 123(3), points (f) and (g)(i)

devices that must bear the carrier on the device itself

9 November 2023	Delegated Regulation (EU) 2023/2197 in force: Master UDI-DI for contact lenses added to Annex VI, Part C, applicable from 9 November 2025	Art. 1 and Art. 2
15 February 2024	Regulation (EU) 2024/568 on fees payable to the European Medicines Agency in force the day after publication; it replaces Article 106(14) on fees for expert-panel advice and applies from 1 January 2025	Art. 14 and Art. 18
26 May 2024	Deadline for legacy-device manufacturers to have a quality management system under Article 10(9) and to lodge a formal application with a notified body, and for class III custom-made implantable devices to apply for conformity assessment	Art. 120(3c), points (d) and (e), and Art. 120(3f)
9 July 2024	Regulation (EU) 2024/1860 in force on the day of publication: gradual roll-out of Eudamed module by module, new Article 10a on supply interruptions, Article 120(8) deleted	Art. 1 and Art. 3
26 September 2024	Deadline for the written agreement between the legacy-device manufacturer and its notified body; from this date that notified body is responsible for surveillance of the devices covered	Art. 120(3c), point (e), Art. 120(3e) and Art. 120(3f)
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. 1, point (1), and Art. 3
26 May 2025	UDI carrier required on the labels of class I devices, and directly on reusable class IIa and IIb devices that must bear the carrier on the device itself	Art. 123(3), points (f) and (g)(ii)
13 October 2025	Delegated Regulation (EU) 2025/1920 in force: Master UDI-DI for spectacle frames, spectacle lenses and ready-to-wear reading spectacles, applicable from 1 November 2028	Art. 1 and Art. 2
9 November 2025	Master UDI-DI rules for standard and made-to-order contact lenses apply (Annex VI, Part C, Section 6.6.1)	Art. 2

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-, 12- and 18-month clocks of Article 123(3)	Art. 1 and Art. 2; Art. 123(3), points (d), (e) and (ea)
1 January 2026	Regulation (EU) 2025/2457 in force: Annex I, Section 10.4 now refers to Category 1 endocrine disruptors under the CLP Regulation and ECHA takes over the guidelines on phthalates and other CMR or endocrine-disrupting substances	Art. 3 and Art. 5
26 May 2026	End of the derogation for class III custom-made implantable devices: from this date they need a notified-body certificate under Article 52(8), second subparagraph	Art. 120(3f)
28 May 2026	Mandatory use of the first four Eudamed modules (actor registration, UDI and device registration, notified bodies and certificates, market surveillance); manufacturers, authorised representatives and importers register in Eudamed instead of national databases	Art. 123(3), point (d)
19 July 2026	Delegated Regulations (EU) 2026/1359 and 2026/1451 in force: longer lists of well-established class IIb implantable devices exempt from device-by-device technical-documentation assessment and of implantable and class III devices exempt from mandatory clinical investigations	Art. 1 and Art. 2; Art. 1 and Art. 2
28 November 2026	Deadline (12 months from the Eudamed notice) for manufacturers to have entered in Eudamed the Article 29 information on devices placed on the market from 28 May 2026, including legacy devices under Article 120(3), (3a) and (3b)	Art. 123(3), point (e); Art. 2
26 May 2027	UDI carrier required directly on reusable class I devices that must bear the carrier on the device itself	Art. 123(3), point (g)(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	Art. 121

28 May 2027	Deadline (18 months from the Eudamed notice) for notified bodies to have entered their certificates in Eudamed; the duties to upload the summary of safety and clinical performance and to notify certificates follow the certificate entry	Art. 123(3), points (ea) and (eb)
31 December 2027	End of the transitional period for legacy class III devices and class IIb implantable devices other than sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors	Art. 120(3a), point (a)
1 November 2028	Master UDI-DI rules for spectacle frames, spectacle lenses and ready-to-wear reading spectacles apply (Annex VI, Part C, Section 6.6.2)	Art. 2
31 December 2028	End of the transitional period for the other legacy class IIb devices, class IIa devices, class I devices placed on the market sterile or with a measuring function, and class I devices up-classified by the regulation	Art. 120(3a), point (b), and Art. 120(3b)

Obligations by role

Manufacturer (including own-brand sellers and reproprocessors)

- 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 clinical evaluation under Article 61 and Annex XIV, including post-market clinical follow-up; for implantable and class III devices a clinical investigation is required unless one of the Article 61(4) to (6) exceptions applies, whose list of well-established devices was extended by Delegated Regulation (EU) 2026/1451. Art. 5(2) and (3), Art. 10(1) to (3) and Art. 61; Art. 1
- 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 clinical evaluation under Article 61 and Annex XIV, including post-market clinical follow-up; for implantable and class III devices run a clinical investigation unless an Article 61(4) to (6) exception applies, whose list of well-established devices Delegated Regulation (EU) 2026/1451 extended. Art. 5(3), Art. 10(3) and Art. 61; Art. 1
- Classify the device into class I, IIa, IIb or III using the 22 rules of Annex VIII and run the matching conformity assessment before placing it on the market: Annex IX (or Annex X with Annex XI) for class III; Annex IX with technical-documentation assessment of a representative device per generic device group for class IIb, and of every device for class IIb implantables other than the well-established types listed in Article 52(4); Annex IX or Annex XI for class IIa; the EU declaration of conformity alone for class I, except that sterile, measuring and reusable surgical class I devices need a notified body for those aspects. Art. 51(1) and Art. 52(1) to (7); Art. 1
- Classify the device into class I, IIa, IIb or III using the 22 classification rules of Annex VIII. Art. 51(1) and Annex VIII
- Before placing the device on the market, run the conformity assessment procedure of Article 52 for its class: a notified body under Annex IX, X or XI for classes IIa, IIb and III, and self-declaration for class I, with a notified body for sterile, measuring and reusable surgical aspects. Art. 52(1) to (7); Art. 1
- Draw up and keep up to date the technical documentation of Annexes II and III (or the Annex XIII documentation for custom-made devices), draw up the EU declaration of conformity with the Annex IV content and the Basic UDI-DI, 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 was placed on the market, 15 years for implantables. Art. 10(4) to (6), Art. 10(8), Art. 19, Art. 20 and Art. 27(6)
- Draw up and keep up to date the technical documentation of Annexes II and III, or the Annex XIII documentation for custom-made devices. Art. 10(4) and (5)
- Draw up the EU declaration of conformity with the Annex IV content and the Basic UDI-DI, and keep it up to date. Art. 10(6) and Art. 19
- 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(6) and Art. 20
- 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, and 15 years for implantable devices. Art. 10(8)
- Operate a quality management system proportionate to the risk class that covers regulatory strategy, risk management, clinical evaluation, product realisation, UDI, 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(9) 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(9) and keeps series production in conformity. Art. 10(9)
- 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 custom-made and investigational devices and to all higher packaging levels, place the UDI carrier on the label and packaging within the staggered dates of Article 123(3), 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. Art. 27(1), (3), (4) and (7), Art. 29(1) and Art. 123(3), points (f) and (g)
- Assign a UDI (UDI-DI and UDI-PI) from a designated issuing entity to each device other than custom-made and investigational devices and to higher packaging levels, place the UDI carrier on the label and packaging by the Article 123(3) dates, and keep the list of UDIs in the technical documentation. Art. 27(1), (3), (4) and (7) and Art. 123(3), points (f) and (g)
- Assign a Basic UDI-DI and submit the Annex VI core data to the UDI database before placing the device on the market. Art. 29(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), 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. 29(4), Art. 31 and Art. 123(3), points (d) and (e); 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. 31; 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. 31; 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. 29(4) and Art. 123(3), points (d) and (e); Art. 1
- Supply the label and instructions for use with the Annex I, Section 23 information in the official language(s) of the Member State where the device reaches the user or patient, with indelible and legible label particulars; provide an implant card and patient information with implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors); and draw up a summary of safety and clinical performance for implantable and class III devices, validated by the notified body and published in Eudamed. Art. 10(11), Art. 18 and Art. 32
- Supply the label and instructions for use with the Annex I, Section 23 information in the official language(s) of the Member State where the device reaches the user or patient, with indelible and legible label particulars. Art. 10(11)
- Provide an implant card and the Article 18 patient information with implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. Art. 18

- For implantable and class III devices other than custom-made or investigational devices, draw up a summary of safety and clinical performance, validated by the notified body and published in Eudamed.

Art. 32

- 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 I devices or a periodic safety update report for class IIa (at least every two years) and class IIb and III (at least annually), submitted through Eudamed to the notified body for class III and implantable devices. Art. 10(10) and Art. 83 to 86
- 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(10), Art. 83 and Art. 84
- Produce a post-market surveillance report for class I devices, or a periodic safety update report for class IIa (at least every two years) and classes IIb and III (at least annually), submitted through Eudamed to the notified body for class III and implantable devices. Art. 85 and Art. 86
- 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, submit trend reports for statistically significant increases in non-serious incidents, and provide a final report. Art. 10(13) and Art. 87 to 89
- 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(13), Art. 87(1)(a) and (3) to (5) and Art. 89
- 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. 87(1)(b) and Art. 89(8)
- Report any statistically significant increase in the frequency or severity of incidents that are not serious incidents, or in expected undesirable side-effects, that could significantly affect the benefit-risk analysis. Art. 88
- 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(12), (14) and (16)
- 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(12)
- 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(14)
- 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(16)
- 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, other than a custom-made 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. Art. 10a and Art. 120(13); 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; if you combine CE-marked devices into systems or procedure packs, draw up the Article 22 statement and register the pack; and do not use claims, names or pictures that mislead on intended purpose, safety or performance. Art. 7, Art. 10(8), third subparagraph, Art. 11(1) and Art. 22
- 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(8), third subparagraph, and Art. 11(1)
- If you combine CE-marked devices, or devices with other products, into a system or procedure pack, draw up the Article 22 statement and register the pack. Art. 22
- 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

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), (6), (7), (9), (10), (11) and (12). 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, 15 years for implantables. Art. 11(3), points (a) and (b), and Art. 10(8)
- 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 was placed on the market, and 15 years for implantable devices. Art. 11(3), point (b), and Art. 10(8)
- Register in Eudamed to obtain your own single registration number, verify that the manufacturer has met its UDI and device registration obligations, and keep your actor data updated and confirmed.
Art. 11(3), point (c), and Art. 31
- Register in Eudamed to obtain your own single registration number, and keep your actor data updated and confirmed. Art. 31
- Verify that the manufacturer has complied with its UDI and 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 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 relabel or repackage, 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 relabelled or repackaged 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.
Art. 13(4), Art. 30(3) and Art. 31
- 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. 30(3)
- Register as an actor in Eudamed to obtain a single registration number before placing devices on the market. Art. 31
- If you are established in Denmark, also notify Lægemiddelstyrelsen of your name, CVR number, contact details, role and the types of devices you import, and report changes and cessation; the national registration is separate from Eudamed and carries a one-off registration fee and an annual market-surveillance fee (bekendtgørelse nr. 1731 af 8. december 2025, § 14; bekendtgørelse nr. 1733 af 8. december 2025, §§ 2 and 3). § 14; §§ 2–3
- 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(8) period, cooperate with competent authorities on risk-elimination measures, and provide free samples or access to the device on request. Art. 13(9) and (10)
- Keep a copy of the EU declaration of conformity and any certificate for the Article 10(8) period: 10 years after the last device was placed on the market, and 15 years for implantable devices. 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)
- 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, 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. 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 and provide free samples or access to the device. Art. 14(6)
- 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 relabelled or repackaged device available. Art. 16(2) to (4)
- Where national law requires it, register as a distributor: in Denmark, distributors and specialist retailers established in Denmark register with Lægemiddelstyrelsen, which stays a national registration outside Eudamed and carries a registration fee and an annual fee under bekendtgørelse nr. 1733 af 8. december 2025; shops that only sell devices at retail are exempt unless they are specialist retailers (bekendtgørelse nr. 1731 af 8. december 2025, § 14, stk. 6, and § 15). Art. 30(2); § 14 and § 15

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 2021. 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 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 the Danish act on medical devices (lovbekendtgørelse nr. 682 af 29. maj 2023, as amended by lov nr. 1759 af 29. december 2025), whose § 3 names Lægemiddelstyrelsen as the competent authority, bekendtgørelse nr. 1731 af 8. december 2025 om medicinsk udstyr m.v. (in force 1 January 2026) and the fee orders bekendtgørelse nr. 839 af 20. juni 2023 (as amended) and bekendtgørelse nr. 1733 af 8. december 2025. Breaches of the MDR and of orders, prohibitions or information duties under it are punishable in Denmark by a fine or imprisonment of up to one year and six months (§ 6(2) of the act on medical devices), with liability for companies (§ 6(4)); failure to make the national notifications of §§ 12 to 15 of bekendtgørelse nr. 1731 is punishable by a fine (§ 20). Art. 113, Art. 10(14), Art. 93 to 99; § 3 and § 6; §§ 12 to 15 and § 20

Checklist

- 1. Confirm the product has an intended medical purpose under Article 2(1) or is an Annex XVI product, and that no Article 1(6) exclusion (IVD, medicinal product, cosmetic, tissues, food) applies; check borderline combinations against the principal mode of action (Article 1(8) and (9)).
- 2. Decide your role for each device: manufacturer, authorised representative, importer or distributor, remembering that own-brand sales, changing the intended purpose, modifying or reprocessing a device make you the manufacturer (Articles 16 and 17).
- 3. Classify the device with the 22 rules of Annex VIII, including the software rule 11 and the implant rule 8, and record the rationale; the class sets the conformity route, the PSUR cycle and the UDI dates.
- 4. Choose and book the conformity assessment: notified body under Annex IX, X or XI for classes IIa, IIb and III and for sterile, measuring or reusable surgical class I devices; the EU declaration of conformity alone for other class I devices (Article 52).
- 5. Build the technical documentation of Annexes II and III with the risk management file, the clinical evaluation plan and report with PMCF, the label and instructions in the Member State languages, and the post-market surveillance plan (Articles 10(4), 61, 83 and 84).
- 6. Set up the quality management system of Article 10(9) 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 27, 29, 31 and 123(3)).
- 8. Draw up the EU declaration of conformity with the Annex IV content, affix the CE marking with the notified body number, and for implantable and class III devices prepare the implant card and the summary of safety and clinical performance (Articles 18, 19, 20 and 32).
- 9. Run vigilance: a procedure that reports serious incidents within 15, 10 or 2 days, field safety corrective actions and notices, trend reports, and a supply-interruption notice at least 6 months ahead (Articles 10a and 87 to 89).
- 10. For legacy devices, map every directive certificate against 31 December 2027 or 31 December 2028, evidence the Article 120(3c) conditions (QMS by 26 May 2024, notified-body application by 26 May 2024, written agreement by 26 September 2024) and apply the MDR post-market, vigilance and registration rules already now (Article 120(3a) to (3d)).

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