

PPE: PPE Regulation (Regulation (EU) 2016/425), explained

The PPE Regulation sets essential requirements for personal protective equipment in the EU, with three risk categories deciding the notified body's role and duties for manufacturers, authorised representatives, importers and distributors. It has applied since 21 April 2018, replacing Directive 89/686/EEC; the emergency procedures added by Regulation (EU) 2024/2748 apply from 29 May 2026.

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

Key facts

Reference	Regulation (EU) 2016/425	Act type	Regulation
In force	20 April 2016	Applies from	21 April 2018
Amended by	Regulation (EU) 2024/2748	Enforced by	National market surveillance authorities enforce the regulation with the powers of Regulation (EU) 2019/1020 (Article 37 still cites Articles 15(3) and 16 to 29 of Regulation (EC) No 765/2008, read as Regulation (EU) 2019/1020 since 16 July 2021); in Denmark, Sikkerhedsstyrelsen, since January 2026 the Markedsovervågning department of Erhvervsstyrelsen, is the control authority for PPE placed on the market under the Danish product act (lovbekendtgørelse nr. 22 of 8 January 2026), having taken over from Arbejdstilsynet on 1 December 2018, while Arbejdstilsynet remains the authority for the use of PPE at work and for made-to-order or third-country PPE for offshore oil and gas activities.

Key dates

9 March 2016	Regulation (EU) 2016/425 adopted by the European Parliament and the Council	title
20 April 2016	Entry into force, the twentieth day after publication in OJ L 81 of 31 March 2016	Art. 48(1)
21 October 2016	Articles 20 to 36 on the notification of conformity assessment bodies and Article 44 on the committee procedure apply, so that notified bodies could be designated before the general application date	Art. 48(2), point (a)
21 March 2018	Article 45(1) applies: deadline for Member States to notify the Commission of their penalty rules	Art. 45(1) and Art. 48(2), point (b)
21 April 2018	The regulation applies in full and Directive 89/686/EEC is repealed; in Denmark, executive order nr. 210 of 14 March 2018 with supplementary Danish-language requirements enters into force the same day	Art. 46 and Art. 48(2); § 10
1 December 2018	Sikkerhedsstyrelsen takes over the control of PPE products placed on the Danish market from Arbejdstilsynet, which remains the authority for the use of PPE at work	
21 April 2019	End of the transitional period: PPE conforming to Directive 89/686/EEC and placed on the market before this date may still be made available	Art. 47(1)
21 April 2023	EC type-examination certificates and approval decisions issued under Directive 89/686/EEC cease to be valid unless they expired earlier; the Commission's five-year power to reclassify risks by delegated act is tacitly extended	Art. 47(2) and Art. 43(2)
28 November 2024	Regulation (EU) 2024/2748 in force: definitions of crisis-relevant goods and internal market emergency mode added to Article 3, Chapter VIa (Articles 41a to 41e) inserted	Art. 3 and Art. 7
22 April 2025	Corrigendum to Regulation (EU) 2024/2748 published: the provision that survives the emergency mode in Article 41a(3) is Article 41c(7), the CE-marking derogation for nationally authorised PPE	Art. 41a(3), second subparagraph (C1)
29 May 2026	Regulation (EU) 2024/2748 applies: the emergency procedures of Chapter VIa can be activated for PPE designated as crisis-relevant goods	Art. 7
30 May 2026	Executive order nr. 488 of 28 May 2026 in force: executive order nr. 210 re-based on the product act, Erhvervsstyrelsen replaces Arbejdstilsynet as designating and complaints authority, Danish/English labelling of crisis-relevant PPE	

Obligations by role

Manufacturer (including brand owners)

- Carry out a risk assessment to identify the risks your PPE protects against, and design and manufacture it to the applicable essential health and safety requirements of Annex II, taking into account the intended and the reasonably foreseeable uses. Art. 5, Art. 8(1) and Annex II, preliminary remarks 4 and 5
- Carry out a risk assessment to identify the risks your PPE is intended to protect against and the essential health and safety requirements that apply to it. Art. 8(1) and Annex II, preliminary remark 4
- Design and manufacture the PPE to the applicable essential health and safety requirements of Annex II, taking into account the intended and the reasonably foreseeable uses.

Art. 5, Art. 8(1) and Annex II, preliminary remark 5

- Classify the PPE into risk category I, II or III according to Annex I and run the matching procedure: internal production control (module A) for category I; EU type-examination (module B) plus conformity to type (module C) for category II; EU type-examination plus either supervised product checks at random intervals (module C2) or quality assurance of the production process (module D) for category III. Art. 18 and Art. 19
- Classify the PPE into risk category I, II or III according to Annex I. Art. 18 and Annex I
- Run the conformity assessment procedure for the category: internal production control (module A) for category I; EU type-examination (module B) plus module C for category II; EU type-examination plus module C2 or module D for category III. Art. 19
- Draw up the Annex III technical documentation, and once conformity is demonstrated the EU declaration of conformity in the Annex IX structure, translated into the languages the Member State requires; affix the CE marking before placing on the market and keep both documents for 10 years after the PPE was placed on the market. Art. 8(2), Art. 8(3), Art. 15 and Art. 17(2)
- Draw up the Annex III technical documentation for the PPE. Art. 8(2) and Annex III
- Once conformity is demonstrated, draw up the EU declaration of conformity in the Annex IX structure, translated into the languages the Member State requires. Art. 8(2) and Art. 15
- Affix the CE marking visibly, legibly and indelibly to the PPE before placing it on the market.

Art. 8(2) and Art. 17(2)

- Keep the technical documentation and the EU declaration of conformity for 10 years after the PPE was placed on the market. Art. 8(3)
- For category III PPE, have the CE marking followed by the identification number of the notified body involved in the module C2 or module D procedure; a pictogram indicating the risk protected against may follow. An EU type-examination certificate is valid for at most five years, and the renewal application must reach the notified body between 12 and 6 months before expiry.

Art. 17(3), Art. 17(4) and Annex V, points 6.1 and 7.4

- For category III PPE, have the CE marking followed by the identification number of the notified body involved in the module C2 or module D procedure; a pictogram indicating the risk protected against may follow. Art. 17(3) and Art. 17(4)
- Renew the EU type-examination certificate, valid for at most five years, by applying to the notified body between 12 and 6 months before it expires. Annex V, points 6.1 and 7.4
- Keep series production in conformity, taking account of design changes and changes to the harmonised standards or technical specifications relied on, and where the risks warrant it sample-test marketed PPE, investigate complaints and keep a register of complaints, non-conforming PPE and recalls, informing distributors. Art. 8(4)

- Keep series production in conformity, taking account of design changes and changes to the harmonised standards or technical specifications relied on. Art. 8(4)
- Where the risks warrant it, sample-test marketed PPE, investigate complaints, keep a register of complaints, non-conforming PPE and recalls, and keep distributors informed of that monitoring. Art. 8(4)
- Mark the PPE with a type, batch or serial number or other identifier and with your name, registered trade name or trade mark and a single postal contact address, on the PPE itself or, where its size or nature does not allow it, on the packaging or in an accompanying document, in a language end-users and authorities can easily understand. Art. 8(5) and Art. 8(6)
- Supply the instructions and information of Annex II, point 1.4, in a language the Member State determines (Danish in Denmark), covering storage, use, cleaning, maintenance, performance levels, obsolescence, markings, the risk protected against, the notified body and the standards applied, and either enclose the EU declaration of conformity or give the internet address where it can be accessed. Art. 8(7), Art. 8(8) and Annex II, point 1.4; § 5
- If you consider or have reason to believe that PPE you placed on the market does not conform, immediately bring it into conformity, withdraw or recall it, and where it presents a risk inform the competent authorities of the Member States where you made it available, with details of the non-conformity and the corrective measures. Art. 8(9)
- On a reasoned request, provide all information and documentation demonstrating conformity in paper or electronic form in a language the authority can easily understand, cooperate on risk-elimination measures, and be able to identify who supplied you and whom you supplied for 10 years. Art. 8(10) and Art. 13
- On a reasoned request, provide the authority with all information and documentation demonstrating conformity, in paper or electronic form and a language it easily understands, and cooperate on measures to eliminate the risks. Art. 8(10)
- Be able to identify to the market surveillance authorities, for 10 years after each supply, any economic operator who supplied you with PPE and any economic operator you supplied. Art. 13

Authorised representative

- Act under a written mandate that at least lets you keep the EU declaration of conformity and the technical documentation at the disposal of the market surveillance authorities for 10 years after the PPE was placed on the market, provide conformity information and documentation on reasoned request, and cooperate with the authorities on risk-elimination measures. Art. 9(2)
- Act only under a written mandate from the manufacturer that sets out the tasks you perform on its behalf. Art. 9(1) and Art. 9(2)
- Keep the EU declaration of conformity and the technical documentation at the disposal of the market surveillance authorities for 10 years after the PPE was placed on the market. Art. 9(2)(a)
- On a reasoned request, provide the authority with the information and documentation demonstrating conformity, and cooperate with it on measures to eliminate the risks of the PPE covered by your mandate. Art. 9(2)(b) and Art. 9(2)(c)
- Do not take over the manufacturer's duty to design and manufacture to the essential requirements or to draw up the technical documentation; those cannot form part of the mandate. Art. 9(1)
- Where the mandate specifies it, lodge the application for EU type-examination, notify the notified body of modifications and ask for the certificate review, affix the CE marking and draw up and keep the EU declaration of conformity on the manufacturer's behalf, and affix the notified body's identification number under its instructions; the manufacturing obligations themselves stay with the manufacturer. Art. 17(3), Annex IV, point 5, Annex V, point 10, and Annex VII, point 7
- Where the mandate specifies it, lodge the application for EU type-examination, notify the notified body of modifications and ask for the certificate review on the manufacturer's behalf; the manufacturing obligations stay with the manufacturer. Annex V, point 10
- Where the mandate specifies it, affix the CE marking on the manufacturer's behalf and, under the notified body's instructions, its identification number. Art. 17(3), Annex IV, point 5, and Annex VII, point 7
- Where the mandate specifies it, draw up and keep the EU declaration of conformity on the manufacturer's behalf. Annex IV, point 5, and Annex VII, point 7
- Be able to identify to the market surveillance authorities any operator who supplied you with PPE and any operator you supplied, for 10 years after each supply. Art. 13

Importer

- Place only compliant PPE on the market, and before doing so check that the manufacturer has carried out the appropriate conformity assessment procedure and drawn up the technical documentation, that the PPE bears the CE marking and is accompanied by the required documents, and that it carries the manufacturer's identification, name and address; hold non-conforming PPE back and inform the manufacturer and the market surveillance authorities where it presents a risk. Art. 10(1) and Art. 10(2)
- Indicate your name, registered trade name or trade mark and a postal contact address on the PPE or, where not possible, on its packaging or in an accompanying document, in a language end-users and authorities can easily understand. Art. 10(3)
- Ensure the PPE is accompanied by the Annex II, point 1.4, instructions and information in the language the Member State determines, and that storage and transport conditions under your responsibility do not jeopardise conformity with the essential requirements. Art. 10(4) and Art. 10(5)
- Ensure the PPE is accompanied by the Annex II, point 1.4, instructions and information in the language the Member State determines. Art. 10(4)
- While PPE is under your responsibility, keep storage and transport conditions from jeopardising its conformity with the essential health and safety requirements. Art. 10(5)
- Where the risks warrant it, sample-test marketed PPE, investigate complaints and keep a register of complaints, non-conforming PPE and recalls, informing distributors. Art. 10(6)
- If PPE you placed on the market does not conform, immediately take corrective measures, withdraw or recall it, and where it presents a risk inform the competent authorities of the Member States concerned with details of the non-conformity and the measures taken. Art. 10(7)
- Keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities for 10 years, ensure the technical documentation can be made available on request, provide conformity information on reasoned request in a language the authority understands, cooperate on risk-elimination measures, and identify suppliers and customers for 10 years. Art. 10(8), Art. 10(9) and Art. 13
- Keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities for 10 years after placing on the market, and ensure the technical documentation can be made available on request. Art. 10(8)
- On a reasoned request, provide the authority with the information and documentation demonstrating conformity in a language it understands, and cooperate on measures to eliminate the risks. Art. 10(9)
- Be able to identify to the market surveillance authorities, for 10 years after each supply, any economic operator who supplied you with PPE and any economic operator you supplied. Art. 13
- If you place PPE on the market under your own name or trademark, or modify PPE already on the market in a way that may affect compliance, you carry the manufacturer's obligations under Article 8. Art. 12

Distributor (wholesaler or retailer)

- Act with due care and, before making PPE available, verify that it bears the CE marking, is accompanied by the required documents and by the Annex II, point 1.4, instructions and information in a language easily understood in the Member State of sale, and that the manufacturer and importer have met their identification and address duties; hold non-conforming PPE back and inform the manufacturer or importer and the market surveillance authorities where it presents a risk. Art. 11(1) and Art. 11(2)
- Keep storage and transport conditions under your responsibility from jeopardising conformity with the essential health and safety requirements. Art. 11(3)
- If PPE you made available does not conform, make sure the corrective measures to bring it into conformity, withdraw or recall it are taken, and where it presents a risk immediately inform the competent authorities of the Member States concerned. Art. 11(4)
- On reasoned request, provide the information and documentation demonstrating conformity, cooperate on risk-elimination measures, and identify suppliers and customers for 10 years. Art. 11(5) and Art. 13
- On a reasoned request, provide the authority with the information and documentation demonstrating conformity, and cooperate on measures to eliminate the risks of PPE you made available. Art. 11(5)
- Be able to identify to the market surveillance authorities, for 10 years after each supply, any economic operator who supplied you with PPE and any economic operator you supplied. Art. 13
- If you sell under your own name or trademark or modify PPE in a way that may affect compliance, you take on the manufacturer's obligations. Art. 12

Penalties

Member States lay down the rules on penalties for infringements of the regulation by economic operators; the penalties must be effective, proportionate and dissuasive and may include criminal penalties for serious infringements. Market surveillance authorities evaluate PPE that presents a risk to health or safety, require corrective action, withdrawal or recall within a period commensurate with the risk, inform the notified body, and if the operator fails to act prohibit or restrict the making available, withdraw or recall the PPE and notify the Commission and the other Member States; compliant PPE that still presents a risk can be treated the same way. Formal non-compliance, such as CE marking affixed wrongly or not at all, a missing or wrongly affixed notified-body number on category III PPE, a missing or incorrect EU declaration of conformity, unavailable or incomplete technical documentation, or absent, false or incomplete manufacturer or importer identification, must be ended and otherwise leads to restriction, prohibition, recall or withdrawal. In Denmark, Erhvervsstyrelsen, which absorbed Sikkerhedsstyrelsen in January 2026 as its Markedsovervågning department, is the control authority under the product act (lovbekendtgørelse nr. 22 of 8 January 2026), which lists the PPE Regulation among the product regulations it enforces and allows the authority to order corrective action, stop sales, withdraw, recall or destroy a product, and to punish breaches of the product regulations with fines or, under aggravating circumstances, imprisonment of up to two years, with liability for companies. Executive order nr. 210 of 14 March 2018, as amended by executive order nr. 488 of 28 May 2026 (in force 30 May 2026, now issued under the product act), adds that PPE may only be placed on the Danish market with the EU declaration of conformity and the instructions in Danish (§ 5), requires crisis-relevant PPE placed on the market under an extended Article 41c(2) authorisation to carry the 'crisis-relevant good' information in Danish or English (§ 5(2)), names Erhvervsstyrelsen as the authority that designates Danish notified bodies and hears complaints about their decisions (§§ 6 and 8), and provides fines for breaches (§ 9).

Art. 45, Art. 38, Art. 40 and Art. 41; § 2, stk. 1, nr. 40, § 9, § 14 and § 37; § 5, § 6, § 8 and § 9

Checklist

1. Confirm the product is PPE under Article 3, point (1): designed to be worn or held for protection against a health or safety risk, or an essential interchangeable component or connexion system, and that none of the five Article 2(2) exclusions applies.
2. Decide your role for each product, remembering that selling under your own brand or modifying the PPE makes you the manufacturer (Article 12).
3. Run the Annex II risk assessment and classify the PPE into category I, II or III against the Annex I lists; category III is decided by the thirteen risks listed there, category I by the five minimal risks (Article 18).
4. Choose the conformity route: module A alone for category I; a notified body's EU type-examination plus module C for category II; EU type-examination plus module C2 or module D for category III, or the category II route for single-unit PPE made for one user (Article 19).
5. Compile the Annex III technical documentation, including the risk assessment, the list of applicable essential requirements, the standards applied, test reports and a copy of the instructions, before placing the product on the market (Article 8(2)).
6. Draw up the EU declaration of conformity in the Annex IX structure, translated into the languages of the Member States of sale, and keep it and the documentation for 10 years (Articles 8(3) and 15).
7. Affix the CE marking to the PPE, or to its packaging and documents where that is not possible, followed by the notified body's number for category III, and add the type or serial number and the manufacturer's and importer's name and address (Articles 8(5), 8(6), 10(3) and 17).
8. Write the Annex II, point 1.4, instructions in the language of each Member State of sale, with performance levels, obsolescence, markings, the notified body and the internet address of the declaration (Article 8(7) and 8(8)).
9. Diarise the five-year expiry of each EU type-examination certificate and lodge the renewal 12 to 6 months before it (Annex V, points 6.1 and 7.4).
10. Set up the corrective-action and notification procedure, 10-year supplier and customer traceability and, where the risks warrant it, a complaints register (Articles 8(4), 8(9), 10(7), 11(4) and 13).

Sources

1. Regulation (EU) 2016/425 on personal protective equipment, consolidated text of 29 May 2026 (EUR-Lex) — <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02016R0425-20260529>
2. Regulation (EU) 2016/425 as published in OJ L 81, 31 March 2016 (EUR-Lex) — <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0425>
3. Document information, dates and relationships for CELEX 32016R0425 (EUR-Lex) — <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32016R0425>
4. Regulation (EU) 2024/2748 on emergency procedures for the conformity assessment, presumption of conformity, common specifications and market surveillance of products (EUR-Lex) — <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R2748>
5. Personal protective equipment (PPE), with the PPE Regulation Guidelines, 5th edition, October 2025 (European Commission, DG GROW) — https://single-market-economy.ec.europa.eu/sectors/mechanical-engineering/personal-protective-equipment-ppe_en
6. Regler for personlige værnemidler (Sikkerhedsstyrelsen, Erhvervsstyrelsen) — <https://www.sik.dk/erhverv/produkter/personlige-vaernemidler/love-og-regler/regler-personlige-vaernemidler>
7. Kontrol med personlige værnemidler (Sikkerhedsstyrelsen, Erhvervsstyrelsen) — <https://www.sik.dk/erhverv/produkter/personlige-vaernemidler/vejledninger/kontrol-personlige-vaernemidler>
8. Sikkerhedsstyrelsen, en del af Erhvervsstyrelsen from January 2026 (Sikkerhedsstyrelsen) — <https://www.sik.dk/sikkerhedsstyrelsen-del-erhvervsstyrelsen>
9. Bekendtgørelse nr. 210 af 14. marts 2018 om indretning m.v. af personlige værnemidler (Retsinformation) — <https://www.retsinformation.dk/eli/lta/2018/210>
10. Bekendtgørelse nr. 488 af 28. maj 2026 om ændring af bekendtgørelse om indretning m.v. af personlige værnemidler (Retsinformation) — <https://www.retsinformation.dk/eli/lta/2026/488>
11. Lov om produkter og markedsovervågning, lovbekendtgørelse nr. 22 af 8. januar 2026 (Retsinformation) — <https://www.retsinformation.dk/eli/lta/2026/22>

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