FREE CHECKLIST | EN ISO 15223-1:2021/A1:2025

EU REP Label Transition Checklist

For manufacturers established outside the EU who name an authorised representative on their labels. The amended symbols standard replaces the EC REP symbol with one that is not country or region specific. This checklist helps you plan the change through your normal label update cycle.

1. What changed

Commission Implementing Decision (EU) 2026/1231 lists the amendment to the harmonised symbols standard. The Decision describes it as:

> **"EN ISO 15223-1:2021/A1:2025 on addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific"**
>
> Commission Implementing Decision (EU) 2026/1231, recital (4)

The Decision defers the withdrawal of the reference to the earlier standard. For EN ISO 15223-1:2021 it states that:

> **"it is necessary to allow for a period of 5 years"**
>
> Commission Implementing Decision (EU) 2026/1231, recitals

2. What the label must carry

The symbol is the format. The obligation to name the representative comes from the MDR itself:

> **"(d) if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative;"**
>
> MDR 2017/745, Annex I, Section 23.2

Symbols themselves are governed by Section 23.1(h):

> **"Any symbol or identification colour used shall conform to the harmonised standards or CS."**
>
> MDR 2017/745, Annex I, Section 23.1(h)

3. Checklist

1. Product inventory

List every product and SKU whose label or packaging carries the EC REP symbol, and confirm which of them require an authorised representative.

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2. Packaging levels

Check each packaging level that carries the representative details: unit label, outer packaging and any shipper label where the details appear.

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3. Artwork and symbol library

Update the central artwork files and the symbol library so new artwork uses the amended symbol.

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4. Standard references

Update references to EN ISO 15223-1 in the technical documentation and the list of applied standards to the A1:2025 version.

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5. Representative name and address

Confirm that the name and the registered address of the authorised representative are complete and legible next to the symbol.

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6. Change control

Record the label change through your existing change control and keep the record with the technical documentation.

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7. Timing

Plan the change for your next scheduled label or packaging update inside the transition period.

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8. Suppliers and distributors

Tell label printers, contract manufacturers, packaging suppliers and distributors which artwork version applies from which date.

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9. Representative change

If you are also changing your authorised representative, align the label change with the date agreed under Article 12 (see section 4).

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10. Instructions for use

Review whether your instructions for use repeat the representative details or the symbol, and update them in the same change if they do.

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4. If you change representative at the same time

A label update is the natural moment to change the representative named on it. Article 12 of the MDR requires the handover agreement to set, among other points:

> **"(b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;"**
>
> MDR 2017/745, Article 12

Medex drafts and runs that agreement for manufacturers who move to us. Our switching cost calculator compares three years with your current representative against a move: medexeurep.com/eu-authorised-representative-switching-cost-calculator

Quotations are from the EUR-Lex texts of Regulation (EU) 2017/745 (consolidated version of 10 January 2025) and Commission Implementing Decision (EU) 2026/1231. This checklist is general information and does not replace a review of your own labels.