



Medical Device Labelling Compliance Checklist

EU, UK and US Market Readiness Guide

This checklist helps regulatory and quality teams quickly review whether a medical device label and IFU meet core regulatory expectations across the EU, Great Britain and the United States.

Use this guide before:

- **Market launch**
- **Technical documentation submission**
- **Notified Body audit**
- **Label redesign or artwork updates**

For each section, mark **Yes / No / N/A**.

Section 1 Product Identification

Confirm the device can be clearly identified and linked to the approved regulatory documentation.

Device name or trade name is clearly stated

Model or reference number is included where required

Intended purpose is clearly identifiable

Product presentation matches the technical documentation or submission

Device variants are clearly distinguished

Common Issue: Labels referencing a device name or indication that differs from the regulatory submission.

Section 2

Manufacturer and Economic Operator Details

Manufacturer

- Manufacturer name is stated
- Manufacturer address is complete and current
- Legal manufacturer matches regulatory documentation

EU Market

- EU Authorised Representative is identified where required
- EU REP details appear on label, packaging, or IFU
- Operator details match technical documentation

Great Britain

- UK Responsible Person is identified where required
- UKRP name and address appear where applicable
- UKRP details are not included unnecessarily on CE-only devices

United States

- Manufacturer or distributor details meet FDA labelling rules
- “Manufactured for” or “Distributed by” wording is used where applicable

Section 3

Conformity Marking and Market Route

Confirm the correct regulatory route is reflected in the label.

EU

- CE marking is present where required
- Notified Body number is included where applicable

Great Britain

- UKCA marking appears where required
- CE and UKCA markings are not incorrectly mixed

General

- Market-specific label versions are controlled
- Label reflects the correct route to market

Section 4

Traceability and UDI

Device Traceability

- Lot number, batch code, or serial number is present
- Production date or expiry date appears where required
- Traceability information is legible and durable

UDI

- UDI is present where required
- UDI is provided in human-readable form
- Machine-readable format is correct
- UDI placement on label or packaging is appropriate
- UDI data matches the regulatory database records

Common Issue: UDI present on packaging but inconsistent with product database entries.

Section 5

Symbols and Standardised Information

Confirm symbols comply with recognised standards and are used correctly.

- Symbols align with ISO 15223-1 where applicable
- Symbols are current and recognised
- Outdated symbols have been removed
- Symbol meanings are explained where required
- Symbols are used consistently across label and IFU

Common Issue: Legacy artwork containing outdated or non-standard symbols.



Section 6

Instructions for Use (IFU)

Confirm IFU content supports safe and effective use.

- Intended user is clearly defined
- Instructions support safe use of the device
- Warnings and precautions are included
- Contraindications are stated where applicable
- Storage and handling instructions are provided
- IFU language versions meet market requirements
- IFU content aligns with label claims

Common Issue: Claims or usage instructions that exceed the approved intended purpose

Section 7

Claims and Safety Information

Confirm product claims are supported by regulatory documentation.

- Performance claims are supported by evidence
- Indications align with regulatory submissions
- Risk warnings reflect known device hazards
- Label and IFU claims match technical documentation

Section 8

Artwork and Change Contr

Confirm label artwork is properly controlled.

- Approved master artwork exists
- Version control is clearly documented
- Obsolete artwork is archived
- Packaging components use the correct label revision
- Label changes trigger regulatory review

Section 9

Final Regulatory Release Check

Before label release confirm:

- Label aligns with technical documentation
- IFU version is current and approved
- Economic operator details are correct
- UDI requirements are satisfied
- Symbols and translations are verified
- Regulatory approval has been documented

Quick Risk Check

Unchecked Items

Risk Level

0-4

**labelling appears
broadly compliant**

5-10

**Moderate risk -
review artwork
and documentation**

10+

**High risk - labelling
system likely requires
remediation**

Patient Guard
Medical Device Quality & Regulatory Assurance



Need Help Reviewing Your Device Labels?

Patient Guard supports manufacturers with:

- EU MDR labelling compliance
- UKCA and UK Responsible Person requirements
- FDA labelling alignment
- UDI implementation
- Technical documentation consistency reviews

Next step...

Book a regulatory labelling review with Patient Guard.
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Regulatory & Quality Specialists

Speak to an expert

Contact us today for more information

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