



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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