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Harmonization of medical device labelling standards: Challenges and opportunities between the EU and US

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ABSTRACT

The labelling of medical devices is a critical component in the safety products, as well as, their understanding by the user and their governmental requirements. Due to the constant integration of the global market, the manufacturer dealing with multiple markets needs to contend with the dissimilar regulatory regimes created by the key regulatory organizations, especially the United States Food and Drug Administration (USFDA) and the European Medicines Agency (EMA) working within the Medical Device Regulation (MDR 2017/745). This is a critical comparison of the labelling requirements of medical device in the US and EU with reference to law provisions, the necessary elements of a label, the required language, the Unique Device Identification (UDI) systems and the post market requirements. Convergence initiatives, regulating manufacturers who are working in two jurisdictions and future leanings to global harmonisation are also raised in the article. The study under consideration should benefit regulatory professionals, manufacturers, and policymakers in such a way that it helps them understand and approach regulatory compliance with labelling in two of the world most influential regulatory systems.

INTRODUCTION

Medical devices are part and parcel of contemporary medical practice, with a very wide scope of technologies that are within the simple tongue depressor up to the complex implantable cardiac defibrillator. Due to the increased use of medical devices worldwide, the importance of clear, standardized, and compliant labelling in the safety of the device, its safe clinical application, and post-market surveillance cannot be overestimated. Labelling in the medical device context is much broader in comparison with the physical label placed on an item. It contains instructions of use (IFU), package insert, manuals, electronic labelling, symbols and any other document or communication that notifies the user with regards to the purpose, operation, maintenance, storage and disposal of the device. A structured label will contain important information to the final users of products, either clinicians, those providing care, or patients, in their overall decision making, risk reduction, and regulatory traceability. The regulatory frameworks, that are prolonged by regulatory authorities of the United States Food and Drug Administration (USFDA) and European Medicines Agency (EMA) under the Medical Device Regulation (EU MDR 2017/745), have an extended regulatory framework of how medical devices should be labelled pre and post market availability. Every jurisdiction has made its own interpretation of the definition of adequate labelling based on the priorities on the protection of public health, legal institutions and market relations (EUMDR, 2017), (USFDA,2020)

In the United States, 21 CFR 801 forms the main requirement of labelling within Title 21 of the Code of Federal Regulations (CFR) and additional information is provided by 21 CFR 820 under Quality System Regulation (QSR). There are devices characterized by Premarket Approval (PMA) whereby the devices are expected to comply with certain labelling expectations as outlined in the approval summaries as well as the guidance documents issued by FDA. (USFDA PMA,2018) Further clarification can be found in the different guidance materials, e.g., Device Labelling Guidance (G91-1 Blue Book Memo). (USFDA,2018) Within the European Union, the labelling of devices is under regulation EU 2017/745, a binding legal regulation that superseded the directive 93/42/EEC Medical Device Directive (MDD). The MDR renews the appropriate labelling requirements on a more resistant level, especially with respect to transparency, information on risks, and possibility to meet the needs of various Member States in terms of language and with digital traceability (the Unique Device Identification (UDI) system).(EUMDR UDI,2017) MDR underlines that CE marking is the significant element of regulatory compliance and, thus, devices must indicate the CE mark and the linked identification of Notified Body on the product label as necessary. (EUMDR CE MARK, 2017)

The US and EU systems have much variation in the format of labelling, scope of the labels, language requirements and post-market requirements despite a common goal of providing medical devices that are safe and efficacious. Such differences may impose significant costs to manufacturers interested in accessing the markets in both regions. The demands of two different but similar quality jurisdictions in terms of regulatory compliance are quite complex to negotiate and, in most cases, demands adjustment of label texts and design. Furthermore, the globalization trend, the emergence of digital health technologies, influence the expediting of the movement towards the harmonization of labelling standards. Global efforts, including the moves by the International Medical Device Regulators Forum (IMDRF) and the World Health Organization (WHO)(Lamph, 2012). are seeking to fill this gap by facilitating convergence and alignments of the labelling requirements, especially in the spheres of digital labelling and UDI adoption. (IMDRF, 2024)

In this review article, the author attempts to provide an in-depth comparative analysis of regulatory labelling requirements imposed by the USFDA and the MDR issued by the EU. Through analysis of regulatory texts, officially endorsed guidance documents and practice it aims at giving to manufacturers, regulatory consultants and academic researchers practical knowledge about:

- The coverage and development of the labelling requirements.
- Structural and content-related difference and similarity.
- Difficulties associated with compliance in a 2-market situation.
- Future trends and opportunities of harmonization among nations.

The paper will achieve this goal through the analysis and can be used as a reference point to develop compliant high quality labelling systems that fulfil not only regulatory considerations in the US and EU, but also seeking an international convergence of regulations.

2. Regulatory Landscape Overview

To have a better perspective, it is critical to understand the regulatory environment, to place in context the manner in which labelling requirements are created, administered and revised, region by region. Although the objectives of the safety of devices through regulation are similar in the United States and the European Union, there are major differences in the regulatory framework and the philosophy in both jurisdictions. US can be described as a centralized, and federal structure via the FDA, with the EU as a decentralized system and composed of numerous national authorities along with Notified Bodies that lie inside a broader process of European Commission governance.

2.1 United States – Food and Drug Administration (USFDA)

USFDA is the core organization that governs the medical devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulation in Title 21 of the Code of Federal Regulations (CFR). (USFDA, 2020) Classification of the devices (Class I, II, III), premarket pathways (510 (k), De Novo, PMA) and labelling requirements all fall under the FDA. The mandate of the agency comprises of providing a truthful but not misleading label together with a statement that will allow the device user to use the device safely and effectively.

Key Divisions Involved:

Centre for Devices and Radiological Health (CDRH) monitors the regulation of medical devices.

Office of Product Evaluation and Quality (OPEQ) -Is in charge of premarket review, labelling reviews and surveillance.

Division of Industry and Consumer Education (DICE) - Gives instructions to manufactures on the rules of labelling.

Core Regulatory Documents:

21 cfr Part 801: Labelling Requirements 21 cfr Part 820: Quality System Regulation (QSR) dealing with design and labelling control PMA Labelling Requirements 21 cfr 814 Device Labelling Guidance (G91 -1 Blue Book Memo) Final Rule Under quid UDI (21 cfr 830) Requires unique device identifiers on labels and packages. Label specification need to comply prior to marketing authorization and revision to labelling usually need additional filing or notification to the FDA. Poor or improper labelling can cause FDA Form 483s, warning letters or even recall of the product.

2.2 European Union – European Commission & Competent Authorities

In comparison to the model of centralized control of the FDA, the European Union applies the multi-level system of control. The European Commission establishes the high-level legal context and the Notified Bodies and Competent Authorities (CAs) are the ones at the national level, who ensure that. The governing current law relating to medical devices is the regulation 2017/745 on medical devices (MDR) (EUMDR, 2017). In May 2021, this regulation went fully into effect, and replaced the Medical Device Directive (93/42/EEC). The MDR has presented rigorous requirements of labelling, post-market surveillance, clinical evaluation and traceability.

Important Bodies Involved:

European commission - DG SANTE: Prepares laws, monitors market activity.

Notified Bodies: Pre CE marking: perform conformity assessment and label review.

Marking of Legal Provisions in MDR:

Part III Information Supplied with the Device 12, UDI System and Labelling 13, Part C 11, Annex VI UDI System 11, Annex V CE Marking 11, Article 20 11

The MDR requires that the labels to be used on the device are made in the national language (languages) of the Member State in which the device is marketed. It consists of pictograms/symbols according to international standards. Display the UDI, CE mark, Notified Body number and manufacturer/importer details. Contain special texts in warnings and precaution statements applicable to the risk category of the device.

Most of the labelling in EU has to be in more than one language unlike in the US hence this is a core challenge that is unique to manufacturers who need to penetrate into all the 27 EU Member States.

3: Scope of Medical Device Labelling

Labelling refers to not only the piece of paper (or sticker) that is attached to a machine but a vast bulk of paperwork and other symbols that convey critical safety, utilization, and regulatory compliance data to customers throughout the product lifespan. Although the US and EU have varying legal terms and format by regions, the two systems identify the entirety of labelling in guaranteeing the good health of the population and regulatory control provisions.

3.1 Labelling of United States (USFDA)

In the Federal Food, Drug, and Cosmetic Act (FD&C Act) and in 21 CFR Part 801, labelling is generously interpreted:

Labelling covers all labels, other written, printed, or graphic materials (1) on any article or any of its containers or wrappers or (2) accompanying such article at any time when a devise is held offered for sale after shipment or delivery to shipment in interstate commerce. FD&C Act 201(m). (USFDA Labelling, 2018) This consists of the label on the device or its box, Instructions for Use (IFU), Packaging inserts, Marketing brochures, Operator manuals, Software instructions, Promotional material (in the event it makes claims about the device). According to the FDA, the meaning of the word accompanying is wide-reaching, it includes printed media as well as websites which are on the site of a manufacturer as long as they fulfil an instructional or promotional goal.

Main Considerations that are identified as Labelling in US:

Name of device, model, serial/lot number, Name, and address of Manufacturer/importer, Indications for use and intended users, Contraindications, warnings, and precautions, (Sterilization method, in case of a nonsterile device), Instructions of use, storage, disposal, UDI (Unique Device Identifier), Label control under 21 CFR 820.120 (part of QSR)

3.2 Labelling of European Union (EU MDR 2017/745)

In the EU MDR the labelling is described as a part of the broader scope called information provided with the device and subject to Annex, I Chapter III. The written, printed or graphic information displayed on the device or on the packaging of each unit of the product or on the packaging of more items is defined as, the label. Instructions for use (IFU) refers to information availed by the

manufacturer to enable the user to know how to safely and efficiently use a device (Article 2(14) & (15)) (MDR, 2019). As opposed to the US, the MDR does not combine the label with the IFU; however, the two elements are regarded as mandatory parts of the device documentation.

Discerned Aspects of Labelling Identified in EU:

Device name, model, reference code, CE marking and the number of the Notified Body, Manufacturer and importer contact details, UDI-DI and UDI-PI, Language translation, per Member State, Date of manufacture and expiry, Reprocessing instructions (in case of reusable devices), Environmental warnings (e.g., re-users, recyclable), Patient information cards (implantable)

Also, within the subject of MDR is the provisions of the label content of symbols where a use of ISO 15223-1 compliant pictograms has to be used where non-text is not provided (ISO 15223,2021).

3.3 Comparative Scope: USFDA vs EU MDR

Scope Item	USFDA (21 CFR, FD&C Act)	EU MDR (2017/745)
Definition of Labelling	Very broad – includes all materials "accompanying" device	More segmented – "label" vs "IFU" as distinct elements
Includes promotional material?	Yes, if it contains regulated claims	Not typically, unless part of regulated IFU or label
UDI requirement?	Yes – 21 CFR 801 & 830	Yes – Annex VI Part C
Symbols	Optional, not mandatory	Mandatory if no text; must follow ISO 15223-1
Language	English only	Official language(s) of the Member State(s)
e-Labelling allowed?	Yes, in limited cases (e.g., software, home-use devices)	Yes, under Commission Regulation (EU) 207/2012

4. Requirements of the United States Medical Devices Labelling (FDA)

The United States the United States Medical device labelling is heavily regulated by the Food and Drug Administration (FDA) under the direction of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations appearing in Title 21 of the Code of Federal Regulations (CFR). The labelling requirements make devices safe, used effectively and as intended and is also a critical part in market authorizations and post market submissions.

The section gives an elaborate analysis of FDA labelling requirements based on regulatory framework, expectations in the content, UDI requirements and enforcement provisions.

4.1 Legal Foundations of Labelling – USFDA

Labelling regulations are scattered across multiple parts of 21 CFR, including:

CFR Part	Subject
21 CFR Part 801	General labelling requirements
21 CFR Part 820	Labelling control under Quality System Regulation (QSR)
21 CFR Part 830	Unique Device Identification (UDI)
21 CFR Part 814	Labelling requirements for PMA (Class III) devices

These two parts provide regulations to various elements of a devices labelling and need to be adhered in totality depending on the type and class of the devices.

4.2 21 CFR Part 801 – General Labelling Requirements

Part 801 includes the general rules the label and labelling which will be applied to every medical device.

Key Provisions:

801.1 Name and address of manufacturer, packer, or distributor 801.4 Intended Use clearly indicated 801.5 Label must include adequate directions for use unless exempted 801.109 Prescription devices should include indications of use, warnings and precautions, technical and clinical information to professionals 801.15 Prominence and readability of the required information 801.18 Prominence of UDI on label and packages. (USFDA 801,1976)

Examples Labels Required:

Terms Name of the device, model name, name and address of manufacturer, the UDI barcode and a human-readable equivalent of that barcode, Lot of serial number, an expiry or date of manufacture, (Remaining), Storage and handling instruction and the prescription legend: Caution: Federal law restricts this device to sale by or on the order of a physician

4.3 21 CFR Part 820 - Quality System Regulation (QSR) and Labelling Control

Part 820 covers the design, manufacture, package, label, store and distribute devices. With QSR, the manufacturers are required to put in place the procedures to regulate labelling processes and the errors that are likely to occur.

Labelling-Specific Sections:

Section 820.120- Device Labelling

- Labels should be checked and accepted before their use.
- The procedures should be enough to avoid mix ups and proper labels should be used.
- The labels should be visible and should be attached in a good manner.

Section 820, 130 packaging

Handling of the devices must be avoided by effectively packaging and labelling them. The FDA is habitual in auditing these procedures and the non-conformance (e.g., labelling failure, lapse in labelling, or misbranded products) is a regular finding of Form FDA 483s and Warning Letters. (USFDA 820, 1996)

4.4 21 CFR Part 830 - Unique Device Identification (UDI)

The UDI Rule which was enacted in 2013 has mandated most medical devices to have a Unique Device Identifier on the label, packaging, and in other cases the device, itself.

UDI Components:

Element	Description
UDI-DI (Device Identifier)	Static portion – identifies the labeller and device model
UDI-PI (Production Identifier)	Dynamic portion – includes lot, serial number, manufacture/expiry date

The requirements are supposed to be presented in the human readable and AIDC (e.g., barcode) form with the UDI data being filed with the FDA Global Unique Device Identification Database (GUDID). (USFDA 830, 2013)

4.5 21 CFR Part 814- Premarket Approval (PMA) Labelling Requirements

Part 814 covers Class III devices, which have got a Premarket Approval (PMA) application owing to their high risk, as well as complexity.

Key Sections:

814.20(b)(10) - PMA should submit all labelling of the device in the outer package including labels on the outer package, instructions to the users (IOU) and patient labelling (where applicable), 814.39 - Labelling changes that are significant (e.g., change of indications

of use, risk information) – It requires a PMA supplement, 814.82 - FDA can place particular conditions on labelling such as warnings, symbols or post-market instructions. The premarket procedure reviews critically PMA labelling. Any modification of labelling done after approval should be processed and approved by the FDA. (USFDA 814, 1986)

4.6 FDA Labelling Enforcement and Compliance Actions

Mislabelling falls under the category of misbranding of the act Sections 502 of the FD&C. Some typical FDA Enforcement are Form FDA 483s - Observations following an inspection (e.g., labelling mistakes, missing control procedures), Warning Letters - Does reported after issue of a Warning Letter, recalling labelling errors are among the most common causes of device recalls, import detention - Devices with noncompliant labels can be detained at US border.

Illustration: A class II device intended to diagnose was recalled due to failure to label the UDI on the exterior packaging and this contravened 21 CFR 801.20 and 830.300.

5. Regulations on medical Devices Labelling in the European Union (MDR 2017/745)

The European Union (EU) has developed an effective and harmonized regulatory framework of medical devices with Regulation (EU) 2017/745 also referred to as the Medical Device Regulation (MDR). It came into full effect May 26, 2021, and this regulation supersedes the Medical Device Directive (MDD 93/42/EEC) and considerably widens the labelling, safety and performance requirements of manufacturers and economic operators. The part focuses on mandatory requirements of MDR labelling, such as compulsory content, UDI, CE marking, language requirements, and requirements of different classes of devices.

5.1 Legal Framework for Labelling in the EU

Labelling requirements in the EU MDR are primarily governed by the following sections:

MDR Section	Description
Article 2(13–15)	Definitions: Label, IFU, UDI
Article 10	General obligations of manufacturers
Article 18	Implantable device information
Article 20	CE marking rules
Article 27–28	UDI system and obligations
Annex I (Chapter III)	Detailed labelling and IFU content requirements
Annex VI (Part C)	UDI carrier requirements

5.2 Labelling Content Requirements (Annex I, Chapter III)

Under MDR Annex I, Chapter III, the label must include the following minimum information:

Required Item	Explanation
Manufacturer name and address	Clearly identified and distinguishable from importers/distributors
Device name and model/reference number	Must allow full traceability
UDI-DI and UDI-PI	In human- and machine-readable (AIDC) formats
Lot or serial number	For traceability and post-market action
Date of manufacture / expiry	At least one required
CE marking	With Notified Body number for Class IIa/b/III
Sterility and sterilization method	If applicable (e.g., EO, gamma)
Intended purpose	Device function and application
Precautions/warnings/contraindications	Essential safety information
Storage/handling conditions	Temperature, humidity, etc.
Information on reprocessing	For reusable devices (e.g., cleaning, sterilization)
Use of symbols	ISO 15223-1 and ISO 20417-compliant if used without text
Language	Must be in the official language(s) of each target Member State

IFUs (Instructions for Use) must be provided unless:

The device is of Class I or 11a and non-hazardous with no elaborate usages. The symbols and the easy-to-read usage indicators replace the IFU. The manufacturer makes a validated eIFU under the Commission Regulation 207Of 2012 (EU). (MDR Annex 1, 2017)

5.3 CE Marking requirements (Article 20 and annex V)

The CE mark is a statement by the manufacturer that his/her product complies with the entire requirements of the MDR.

Key Requirements:

A CE mark has to be attached to the device, to the packaging, and the IFU where possible. In case of Class IIa, IIb and III equipment, the CE mark should have an additional Notified Body code affixed to them (e.g., 0123, which is the code of the TUV SUD). It requires the CE mark to be Visible, legible and indelible and it must be at least 5mm in height (stretching permitted). Misuse of CE mark or wrong usage is a major non conformity and Competent Authorities can impose penalties. (MDR Annex 5, 2017)

5.4 Unique Device Identification (UDI) & Article 27 & Annex VI, Part C

A new UDI system required by the MDR enhances traceability, post market surveillance and field safety measures.

UDI Requirements:

Element	Description
UDI-DI	Device Identifier (fixed portion identifying model/version)
UDI-PI	Production Identifier (lot, serial number, expiry date)
UDI Carrier	Barcode or RFID (machine-readable) and text (human-readable)
Placement	Must appear on label, packaging, and sometimes directly on the device

Part C Technical UDI Labelling Rules Annex VI:

- UDI format is subject to ISO/IEC 15459.
- The employed issuing bodies are the known ones: GS1, HIBCC, ICCBBA.
- UDI should be included in higher levels of packaging (e.g., shipping boxes).
- UDI data should be registered in the EUDAMED with the devices.

Devices that are reusable should not have UDI directly labelled on them but handwriting is acceptable when technically impossible. (MDR Annex 6, 2017)

The implementation Timeline of UDI:

Device Class	UDI Deadline
Class III & implantable	May 2021

Class IIa and IIb	2023
Class I	2025

5.5 Requirements of Language and Symbols

Any label (including IFUs and packaging) should be translated to the official language(s) of the EU country where the device will be on the market. Reduction of language burden and to achieve more clarity and international harmonization may adopt standard symbols included in ISO 15223-1 and ISO 20417. The IFU should contain an explanation of non-standard symbols.

5.6 labelling: Implantable and Reusable Devices

The manufacturers are required to post Implant cards in the names, type of device, UDI and contact of the manufacturer and their Warnings, MRI compatibility, precautions, Information leaflets 2 patients (plain language).

The reprocessing dossier must contain reprocessing guidelines, restrictions on reuse (e.g., maximum cycles), post reuse residual risks and permanent marking of the device with the UDI.

5.7 Consequences of Non-Compliance in EU

Devices can be refused a CE mark, removed to the EU market, prohibited to register in EUDAMED, exposed to Corrective Action Requests (CARs) of notified bodies, placed on field safety notices or recalled. The Competent Authorities can also apply an administrative fine and make the problem public through national databases and EU safety websites.

6. Comparative Labelling Requirement in the US and EU

Labelling of medical devices in the United States (under the FDA), as well as in the European Union (under EU MDR 2017/745), is a fundamental regulatory aspect, as an effective labelling is a guarantee of safe application, device traceability, and broad regulatory compliance. The aims of the two jurisdictions are the same, but there are some significant differences between the terminologies, formatting expectations, and regulatory frameworks, which must be realized by the global manufacturers in order to remain compliant in both jurisdictions.

6.1 Regulatory Structure Comparison		
Feature	United States (FDA)	European Union (MDR)
Regulatory Body	FDA (Centre for Devices and Radiological Health - CDRH)	European Commission, Competent Authorities, Notified Bodies
Primary Regulation	FD&C Act, 21 CFR Parts 801, 820, 830, 814	Regulation (EU) 2017/745 (MDR)
Device Classification	Class I, II, III	Class I, IIa, IIb, III
Label Review	Required for PMA and 510(k) devices	Reviewed for Class IIa, IIb, and III via Notified Bodies
Enforcement Mechanism	Warning letters, recalls, import alerts	NB audit findings, CE mark withdrawal, market suspension
6.2 Label Content Requirement Comparison		
Requirement	US (FDA)	EU (MDR)
Manufacturer name & address	Mandatory (21 CFR 801.1)	Mandatory (Annex I, Sec. 20.1a)
Device identifier/model	Mandatory	Mandatory
Lot or serial number	Mandatory	Mandatory
Manufacturing/expiry date	Required if relevant	Mandatory (either or both)
Sterility and sterilization method	Required if applicable	Mandatory
Intended purpose	Required in IFU	Mandatory on label or IFU
Storage/handling conditions	Required if relevant	Mandatory
Warnings and precautions	Must be present in IFU	Required on label and/or IFU
CE mark	Not applicable	Mandatory
FDA registration number	For listing; not on label	Not applicable
UDI	Mandatory (21 CFR 801.20, 830)	Mandatory (Article 27, Annex VI)
UDI submission database	GUDID	EUDAMED
Use of symbols	Optional; text preferred	Mandatory if text is omitted; must follow ISO 15223-1
Patient implant card	Not required	Required for implantable (Article 18)
Language requirements	English only	Official language(s) of Member States
6.3 UDI Comparison: US vs EU		
Feature	US FDA	EU MDR
Governing Regulation	21 CFR 830	MDR Article 27, Annex VI

UDI Components	UDI-DI (device ID), UDI-PI (production ID)	Same (DI + PI)
Format	Human-readable + machine-readable (AIDC)	Same
Data Submission	GUDID	EUDAMED
Direct Part Marking	Required for reusable devices	Required unless technically infeasible
Labelling Level	Unit label, package, and sometimes direct device	Same
Acceptable Issuing Agencies	GS1, HIBCC, ICCBBA	Same
6.4 IFU and Language Requirements		
Feature	US	EU
IFU Mandatory?	Only for prescription/high-risk devices	Yes, unless exempt (Annex I, Sec. 21)
IFU Format	Paper or electronic (limited scope)	Paper or eIFU (per Regulation 207/2012)
Language	English	Official language(s) of each destination country
Plain language for patients	Encouraged, not always required	Mandatory for implantable and some devices
6.5 CE Marking vs FDA Approval/510(k)		
Feature	CE Marking (EU)	FDA Approval/510(k) (US)
Affixed on device	Required on device and packaging	Not used
Indicates	Conformity with EU MDR	Device is cleared/approved by FDA
Includes Notified Body number?	For Class IIa, IIb, III	Not applicable
Use in advertising	Permitted	FDA clearance/approval status must be properly disclosed
6.6 Enforcement and Post-Market Consequences		
Area	US FDA	EU MDR
Labelling audit	FDA inspections and Form 483	NB surveillance audits
Noncompliance action	Warning letters, recalls, import alerts	CE mark suspension, FSCA, Competent Authority notice
Labelling errors among top recall causes?	Yes	Yes
Labelling change requirements	Submit PMA supplement or new 510(k)	Notify NB; possibly re-certify CE marking

Difficulties and Lack of Harmonization of US and EU Regulation Regarding Requirements relating to Labelling of Medical Devices

Despite the similar intention of both the United States and the European Union to guarantee the safety of patients, traceability of devices, and monitoring of the market using the medical device labelling, there exist some major distinctions in the way in which these goals are achieved. Multinational manufacturers who want to market appliances in the two markets may constantly find cumulative procedures, regulatory drag, and varying compliance cycles. This part investigates the fundamental obstacles and systematic gaps that prevent alignment of the labelling conditions among these two most significant management regimes.(Songara, Raiendra K,2010)

7.1 The Disparate Regimes

Structural difference in mechanisms used in regulation of medical devices is one of the most basic problems:

Feature	US (FDA)	EU (MDR)
Centralized vs Decentralized	Centralized under FDA	Decentralized (EU Commission, Notified Bodies, Competent Authorities)
Pre-market label review	Direct review by FDA	Indirect via Notified Body for high-risk devices
Enforcement	Single national authority (FDA)	Multiple national authorities across Member States

Implication: Companies will have to customize labelling approaches and path to the authorization of two distinct ecosystems with little mutual acceptance.

7.2 UDI Implementation gaps

Despite the similarity of requirements imposed in the two jurisdictions in relation to Unique Device Identification, there remain some important differences:

Issue	Description

Different submission databases	US uses GUDID; EU uses EUDAMED (not fully operational as of 2025)
Deadlines not synchronized	US UDI fully phased in by 2022; EU Class I devices have until 2025
Direct part marking rules differ	Exemptions and conditions vary slightly
Labelling format differences	US requires UDI on labels/packages in both AIDC and HRI; EU format rules are stricter under Annex VI

Outcome: The manufacturers will have to retain two different labelling systems leading to more regulatory compliance and complexity of the chain.

7.3 Multi-lingual Labelling

EU MDR requires information relative to labels and IFUs to be provided in any and every one official language of the member states an equipment is sold in. By comparison, the US FDA labelling has to be in English only. Drawbacks are: translation expenses, validation, formatting difficulties, heightened intricacy of the packaging, chance to bring misunderstanding or improper use of the symbols. An example may be a Class IIa wound dressing that would have the labelling in French, German, Spanish and Dutch so that it could be sold in the EU, and have only English on it to be sold in the US.

7.4 Difference in use of symbols and standards

EU MDR requires adoption of ISO 15223-1 and ISO 20417 symbols in situations where there is no text with them. The use of symbols is optional in the US, and must be clarified, unless classically recognized and generally acknowledged (as defined in the 2016 Symbol Rule of FDA[1]).

Effect: The manufacturers may in many occasions be forced to revise artwork or labelling files to the symbol regulations in the respective region, thus adding cost and delays in production.

7.5 Reuse Device Labelling and Reprocessing Instructions

EU MDR implements a mandatary course of detailed reprocessing instructions, and the last permissible number of reuses, applicable to reusable devices (Annex I, Sec. 23.4). Within the US, although the standardization of reprocessed info is not mentioned in 21 CFR 801 and 820, they are more prescriptive in this regard.

Gap: There is no harmonized format and validation criteria of cleaning/sterilization labelling, which translate to challenge in regulatory review when the product undergoes a 510(k)/PMA or CE mark audit.

7.6 The lack of harmonized e-Labelling Policies

US FDA allows the use of electronic Instructions of Use (e-IFU) in rare situations normally home use devices or devices which do not require the active use of hardware. The EU, through Regulation (EU)207/2012 creates wider opportunities in the use of e-IFUs, notably in Implantable, Fixed installed equipment and Professional-use items

Barrier: The rate of global digitalisation in the field of labelling is hindered by the disjointed adoption of e-labels particularly in the case of equipment that is operated in more than one country.

CONCLUSION

Medical device labelling regulation is central to patient safety, good utilization of products and optimal visibility to regulatory compliance. The United States and the European Union both have elaborate systems in place, in the form of FDA and the EU MDR 2017/745 respectively, to regulate the labelling and marketing and tracking of devices over their life span. Although such frameworks are harmonized in their high-level objectives, their philosophy of regulation, the material to be labelled and the enforcement all vary significantly.

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