European MDR IFU Regulatory Compliance

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Whitepaper

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Abstract

The advancement in medical technology has improved a person's life expectancy and made complex systems more compact and easier to use. Hence, they are no longer found only at the doctor's office or hospital, but also at homes and many other places where they may not necessarily be handled by a trained professional – which increases the risk of misuse and other complications. This has led the manufacturers and regulatory authorities to provide more clarity, ease of use / operation, and clearer information regarding a medical product to the user through labeling.

The type and extent of information that a device label needs to impart is governed by the relevant safety and shipping laws to ensure that the product is used safely and in a more efficient way. It should be noted that labeling not only refers to the content present on the package surface, but ãlso refers to any other additional document that comes with the device – user manuals, leaflets, quick start guides, instructions for use, etc., as stated in some regulations.

This whitepaper explores the new requirements for information that must be imparted in the instruction for use, in order to comply with the European Medical Devices Regulation (MDR 2017/745) and also which necessitate attention from global manufacturers when distributing products.

Abbreviations

Sl. No.	Acronyms	Full form
1.	AIMDD	Active Implantable Medical Devices Directive 90/385/EEC
2.	CAPA	Corrective and Preventive Action
3.	CE	Conformite Europeene
4.	CMR	Carcinogenic, Mutagenic or Toxic to Reproduction
5.	CER	Clinical Evaluation Report
6.	DoC	Declaration of Conformity
7.	DoA	Date of Application
8.	EU	European Union
9.	EUDAMED	European Database on Medical devices
10.	e-IFU regulation	Regulation (EU) Number 207/2012 on Electronic Instructions for Use
11.	GSPR	General Safety and Performance Requirements
12.	GDPR	General Data Protection Regulation
13.	HCL	Hindustan Computer Limited
14.	IC	Implant Card
15.	ISO	International Organization for Standardization
16.	IFU	Instructions for Use
17.	MDR	Medical Device Regulations 2017/745
18.	MDD	Medical Devices Directive 93/42/EEC
19.	MDCG	Medical Device Coordination Group
20.	RS	Restricted Substances
21.	SSCP	Summary of Safety and Clinical Performance
22.	UDI	Unique Device Identification
23.	SME	Subject Matter Experts

Introduction

Labeling is the display of any information about a product on its label and is a part of branding, which helps in product identification. It is a typically printed information that is bonded to the product for easy recognition, and contains specific information such as the name of the product, the company that manufactured it, the type of product, and its intended use.

In the medical industry, labeling not only helps in identifying individual devices but also assists in communicating information related to its safe use and intended performance to health care professionals, patients and other users of medical devices. This information can be displayed on the product itself, or as an insert for the packaging, or as information for use. Labeling and instructions for use (IFU) definitions are given in Figure 1.

Labelling
ISO 13485:2016
label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents

Instructions for use
MDR 2017/745
information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken.

Fig.1: Labeling and IFU Defintions

Various types of labeling are available based on the need and regulatory jurisdiction. Some of them are listed below.

i. Device label including package labels

ii. Instruction for use (IFU)

iii. Implant card (IC)

iv. Patient information document

Based on the intended use of a device and the risk category, the labeling requirements of MDR (European Medical Device Regulations 2017/745) supersedes the previous directives MDD (Medical Devices Directive 93/42/EEC) and AIMDD (Active Implantable Medical Devices Directive 90/385/EEC) by including numerous changes that may need to be implemented for compliance.

Media that can be Used for Publishing Instructions for Use

Manufacturers can provide IFU in paper or electronic format or both. This can be provided along with the medical device or separate, depending on the type of information it carries.

Examples of information supplied separately from the device are given below.

- Information displayed on a screen incorporated into the device
- Electronic IFU (e-IFU)
- Machine readable sources

Manufacturers can select the media and format of the IFU based on the intended user of the particular device and medium. If the media is other than paper form, it shall have an obligation toward the following as stated by the regulation.

- Provide clear information on how to view and access the correct version of IFU
- Way to obtain a paper version of the IFU
- Should provide further copies to the user without any additional cost if requested

Regulation (EU) Number 207/2012 has already stated that "Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in e-IFU Regulation or in any subsequent implementing rules adopted pursuant to this Regulation."

The decision to supply the IFU in electronic form instead of paper format is constrained to certain medical devices.

In order to assess the appropriateness of e-IFU, risk analysis should be performed.

For example, the below devices are meant to be used exclusively by professional users and not likely to be used by a lay person. Hence, their instructions may be provided in electronic form. Devices intended for exclusive use by a lay person may be provided in paper IFU form.Table 1 lists the devices which are part of Regulation (EU) No 207/2012:

Applicable Devices	**Examples**
Active implantable medical devices and their accessories covered by Directive 90/385/EEC intended to be used exclusively for the implantation or programming of a defined active implantable medical device.	Active implantable devices: • Implantable cardiac pacemakers • Implantable defibrillators • Implantable neurostimulators Active implantable devices accessories: • Leads, electrodes, adaptors for implantable cardiac pacemakers and defibrillators.

Applicable Devices	Examples
Implantable medical devices and their accessories covered by Directive 93/42/EEC intended to be used exclusively for the implantation of a defined implantable medical device.	Implantable devices: • Ligaments • Shunts • Stents and valves (e.g. pulmonary) • Nails and plates • Intra-ocular lenses Implantable devices accessories: • Sleeves for screws
Fixed installed medical devices	X-ray machines and CT scanners
Medical devices and their accessories fitted with a built-in system visually displaying the instructions for use	Mobile medical devices. ECG apps and patient monitors
Stand-alone software covered by Directive 93/42/EEC	Software as a medical device

Table 1: e-IFU applicable devices as per Regulation (EU) No 207/2012

Another new requirement of the medical device regulations is that if the manufacturer has a website, then a web-based eIFU multi-language portal is needed to manage the update of IFUs and its distribution globally, thereby ensuring enhanced patient safety and engagement. This information can be accessed anytime from the manufacturer's website using the internet, or with the help of machine-readable sources (GSPR 23.1). Overall the means chosen should be suitable for the anticipated user group and easily available to them.

Language Requirements for Instructions for Use (IFU)

Article 10 (10) Regulation (EU) 2017/745 which discusses the general obligation of manufacturers, states that "Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official union language(s) determined by the member state in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient."

Also, information to be supplied by the manufacturer as stated in Annex II Section 2 of the medical device regulations clearly points out that the instructions for use has to be in the local language as accepted by the member state where the device is envisaged to be sold.

Unlike the previous directives where the translations were completed after CE marking, under MDR translations of the IFUs must be done at an earlier stage in the workflow, as they are submitted as part of the technical documentation to the pertinent notified body for the assessment of conformity.

It is also advisable to minimize the text that requires translation by using internationally recognized symbols / harmonized standards (according to EN ISO 15223-1) or common specification and illustrations, which can also help in reducing the translation costs. (GSPR 23.1(h))

Need for IFU/ Patient Information Document / Implant Card

Instructions for use:

The MDR states that IFU is required for all class IIb and class III medical devices, while class I and class IIa medical devices are exempted if the devices can be used safely without any instructions. (GSPR 23.1(d)). However, if these devices require specific instructions related to cleaning, sterilization and re-use, an IFU will be required.

Patient information and implant card:

According to Article 18 of MDR, implant cards and patient information have to be provided for implantable medical devices that are introduced in to the human body (defined as per Article 2(5)). However, they are not applicable to implants that come under Well Established Technology (WET) like sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors. In accordance with Article 115, Commission will amend this list by adding other types of implants to it or by removing implants therefrom.

Special Cases

MDR has special cases which are more detailed in Figure 2.

Article 17 Single-use devices and their reprocessing	Article 16 Cases in which obligations of manufacturers apply to importers, distributors or other persons
Reprocessor (natural or legal person) of single-use devices shall be considered as a manufacturer. Both original single-use device manufacturer name and reprocessor name shall be mentioned in IFU. The label doesn't need the original single-use device manufacturer name, but reprocessor name is mandatory.	Manufactures shall translate the IFU based on member states' official union language(s). In some cases, the importer or distributor want to sell the device to member states for which the original manufacturer has not performed any translation. In this circumstance, the distributor or importer will translate the IFU and makes available on the market a device under its name, registered trade name or registered trade mark (Article 16 2(a)). In this case, the manufacturer's obligations shall apply to importers, distributors, or other persons who perform the translation.

Fig .2: Special Cases

Business Needs

European medical device manufacturers have a prerequisite to prepare specific IFU as per GSPR 23 Chapter III requirements regarding the information supplied with the device to comply with MDR- regulation 2017/745. Compared with MDD, MDR brings a lot of changes that need to be implemented.

The reusable device manufacturer shall provide information to indicate the situations where the device is no longer to be reused.

Implantable device manufacturers (excluding WET) shall provide the implant card and information to be supplied to the patient with an implanted device according to Article 18. Patient information document is a new deliverable and requirements are available in GSPR under section 23 .

The manufacturer also need to check the applicability of paper IFU vs electronic IFU, and up-to-date IFUs shall be made available on the website.

Article 7 prohibits the manufacturer to use the information in the form of text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance. IFU needs to be updated to align manufacturer claims.

Solution

a. Process Flow for IFU

The following flowchart (Figure 3 & 4) provides the clear guidance and strategy for performing the IFU and patient information document process flow as per MDR .

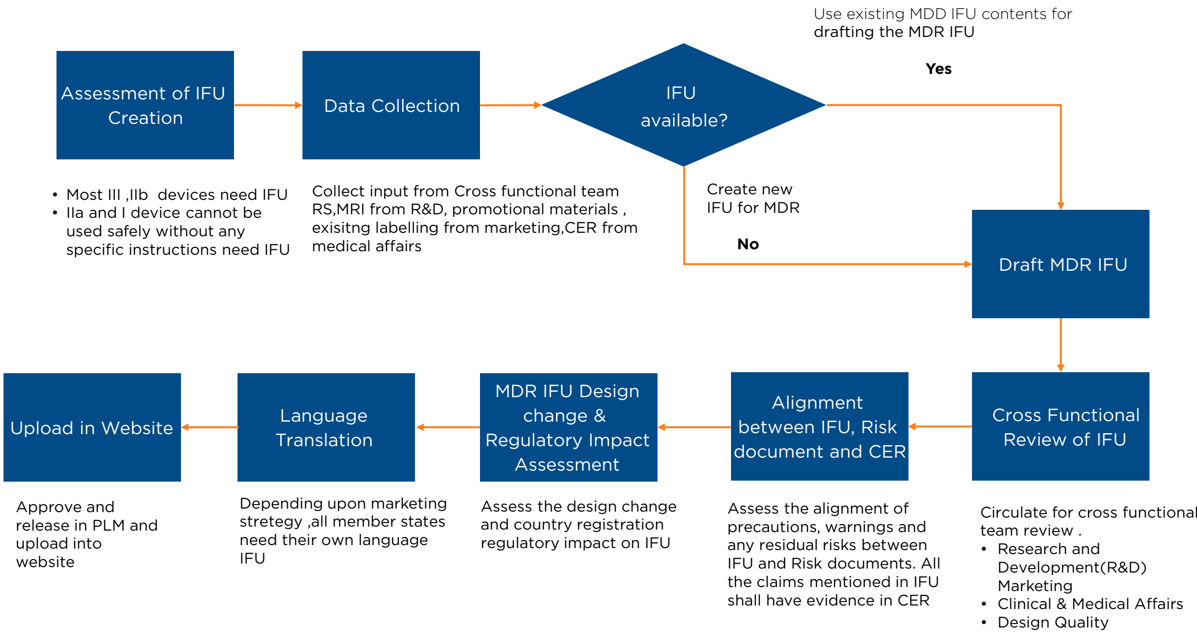


Fig. 3: IFU Activities Process Flow

b. Process Flow for Patient Information Document

As mentioned in MDR Article 18, patient information document shall be written in a way that is readily understood by a lay person and shall be updated where appropriate.

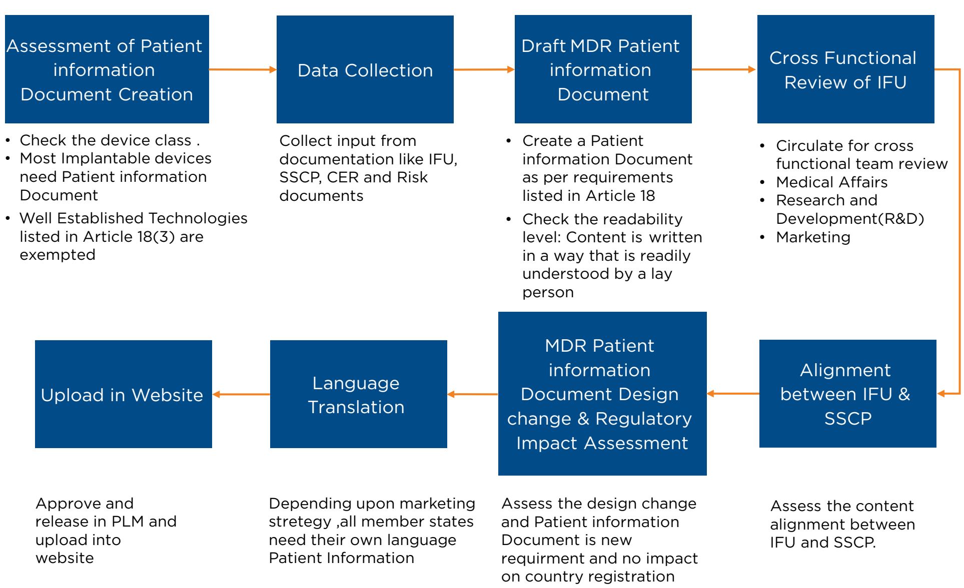


Fig.4: Patient Information Document Activities Process Flow

c. IFU Content

Table. 2 provides the IFU content, source documents (inputs), extent of information to be included, and applicable classes. This table also differentiates new MDR IFU requirements vs MDD requirements.

Legend:

(green)	Common requirements. Same requirement already covered in MDD MDD=MDR
(yellow)	Partially covered in MDD. MDR has additional requirements
(pink)	New requirements. MDR additional requirements not covered in MDD

IFU Content	Information Included	Source	Applicable Classes	MDR/MDD Applicability		MDR/MDD Reference Section	
				MDR	MDD	MDR	MDD
IFU document number & revision	Provide issue date and revision date of the IFU	Not applicable	All classes	Yes	Yes	23.4(y)	13.6(q)
IFU name	Mention name or trade name of the in-scope products device family	Product description	All classes	Yes	No	23.2(a)	New
IFU family overview	Provide short description of the device. Include size, types, packaging configuration etc.	Surgical technique, MDD CER	All classes	Yes	No	23.2(a)	New
Legal manufacturer	Mention name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business	Not applicable	All classes	Yes	Partially covered	23.2(c)	13.3 (a) NEW: "Registered" trade name and "or registered trade mark" and "address of his registered..."
	Manufacturer website where IFU made available	Not applicable	e-IFU applicable devices	Yes	No	23.1	New
Materials	List the materials and associated standards	Drawings	Implants (IIa,IIb,III)	Yes	No	23.2(r)	New
Restricted substances (RS)	List CMRs and endocrine-disrupting substances containing material	RS evaluation report	All classes	Yes	No	23.2(f) 23.4(s)	New

IFU Content	Information Included	Source	Applicable Classes	MDR/MDD Applicability		MDR/MDD Reference Section	
				MDR	MDD	MDR	MDD
Intended use/ purpose	List intended use. This needs to be aligned with CER, Annex II technical documentation report, surgical technique (if applicable), DoC and MDD Techfile (if applicable)	CER, Annex II technical documen-tation report, surgical technique (if applicable), and MDD Techfile (if applicable	All classes	Yes	Partially Covered	23.4(b)	**13.4.** NEW: Clear specification of indications, contra-indications, the patient target groups, and the intended users
Indications	List indications. This needs to be aligned with CER, Annex II technical documentation report, surgical technique (if applicable), and MDD Techfile (if applicable). In many cases, instruments will not have specific indications. Indications are usually based on implants rather than instruments	CER, Annex II technical documen-tation report, surgical technique (if applicable), and MDD Techfile (if applicable)	All classes				
Contra-indications	List contra-indications. This needs to be aligned with CER, Annex II technical documentation report, surgical technique (if applicable) and MDD Techfile (if applicable). In many cases, instruments will not have specific contra-indications. Contra-indications are usually based on implants rather than instruments	CER, Annex II Technical documen-tation report, surgical technique (if applicable), and MDD Techfile (if applicable)	All classes				

IFU Content	Information Included	Source	Applicable Classes	MDR/MDD Applicability		MDR/MDD Reference Section	
				MDR	MDD	MDR	MDD
Patient target group	List patient target groups. This need to be aligned with CER, Annex II technical documen-tation report. In many cases instruments will not have specific patient target groups. Patient target groups are usually based on implants rather than instruments	CER, Annex II technical documen-tation report	All classes	Yes	Partially Covered	23.4(b)	**13.4.** NEW: Clear specification of indications, contra-indications, the patient target groups, and the intended users
Intended users	List intended users. This need to be aligned with CER, Annex II technical documentation report.	CER, Annex II technical documen-tation report	All classes				
Clinical benefits	List clinical benefits. This need to be aligned with CER. In many cases, instruments will not have clinical benefits. Clinical benefits are usually based on implants rather than instruments.	CER	All classes	Yes	No	23.4(c)	New
	Provide the EUDAMED SSCP link	CER	Class III and implantable	Yes	No	23.4(d)	New
	Justification for absence of a clinical benefit and the risks related to the use for devices without a medical purpose	Not applicable	Devices without an intended medical purpose as in Article 1(2)	Yes	No	23.4(x)	New

IFU Content	Information Included	Source	Applicable Classes	MDR/MDD Applicability		MDR/MDD Reference Section	
				MDR	MDD	MDR	MDD
Performance characteristics	Provide performance characteristics. This needs to be aligned with intended use	CER	All classes	Yes	Yes	23.4(e)	13.6(b)
Residual risks and undesirable side-effects	Identify residual risk and side effects from risk documents and list	Risk documents	All classes	Yes	No	23.4(g)	New
Special facilities, or special training, or particular qualifications of the device user and/or other persons	Provide any device user training or qualification of device user or special facilities	Not applicable	All classes	Yes	No	23.4(j)	New
	Circumstances when lay person contact the healthcare professional	Not applicable	Devices used by laypersons	Yes	No	23.4 (w)	New
Device handling information	Provide handling of the device before it is ready for use or during its use - final assembly - sterilization - levels of disinfection and methods	Not applicable	All classes	Yes	Partially Covered	23.4(i)	13.6 (i) NEW: MDR but more detailed
	Provide installation or calibration	Not applicable	Devices that need installation/ calibration	Yes	Partially Covered	23.4(k)	13.6 (d) NEW: MDR but more detailed
Combination of devices	Provide safe combination and any known restrictions	Verification and validation reports surgical technique	All devices	Yes	Yes	23.4(q)	13.6(c)
Warning and precautions	List device-specific warnings and precautions identified in risk documents. Related to malfunction of the device or changes in its performance that may affect safety	Risk documents	All classes	Yes	Partially Covered	23.4(s)	13.6(k) NEW: Malfunction of the device

IFU Content	Information Included	Source	Applicable Classes	MDR/MDD Applicability		MDR/MDD Reference Section	
				MDR	MDD	MDR	MDD
Exposure	List the precautions and measures to be taken as regards exposure to reasonably foreseeable external influences or environmental condition such as radiation, humidity and temperature etc.	Risk documents Verification and validation documents	All classes	Yes	Yes	23.4(s)	13.6(l)
Magnetic resonance environment	Provide the risk of electromagnetic interference or other interference during diagnostic investigations or therapeutic treatment	Verification and validation documents	All classes	Yes	No	23.4(s)	New
Disposal	Provide the safe disposal of the device, accessories, and consumables.	Surgical technique	All classes	Yes	No	23.4(v)	New
Device problem reporting Trouble-shooting	Provide the circumstances in which the user will contact the manufacturer or a competent authority	Not applicable	All classes	Yes	No	23.4(z)	New
Software	Describe selection of the corresponding software, hardware, and accessories	Not applicable	Devices that incorporate electronic programm-able systems, including software, or software that are devices in themselves	Yes	No	23.4(f)	New

IFU Content	Information Included	Source	Applicable Classes	MDR/MDD Applicability		MDR/MDD Reference Section	
				MDR	MDD	MDR	MDD
Sterile device	Provide the symbols for sterile state and sterilization method. Do not use when packaging is damaged.	Sterilization reports	Class Is, IIa, IIb, III	Yes	Partially Covered	23.3(l)	13.3(c) 13.3 (m) 13.6 (g) New: Or un-intentionally opened before use
	List any treatment or handling needed before the device can be used	Not applicable	Class Is, IIa, IIb, III	Yes	No	23.4(j)	New
Non-sterile device	List any treatment or handling needed before the device can be used	Not applicable	All classes except Is	Yes	No	23.4(j)	New
Single-use device	Provide a symbol for single use. List of risks posed due to re-use of single use devices and if IFU is not applicable	Not applicable	IIa, IIb, III	Yes	Partially Covered	23.4(p) 23.4(n)	13.3 (f) 13.3 (h)
Reusable device	Provide information to identify when the device should no longer be reused, e.g., signs of material degradation or the maximum number of allowable reuses.	Not applicable	All reusable devices including Class Ir	Yes	No	23.4(n)	New
	An indication that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the legislation	Not applicable	All reusable devices including Class Ir	Yes	No	23.4(o)	New
Measuring device	Provide short device description and degree of accuracy	Not applicable	Class Im	Yes	Yes	23.4(h)	13.6(p)

IFU Content	Information Included	Source	Applicable Classes	MDR/MDD Applicability		MDR/MDD Reference Section	
				MDR	MDD	MDR	MDD
Radiation emitting devices	Provide type of emitted radiation and how to protect the user from unintended radiation during use	Not applicable	devices	Yes	Yes	23.4(r)	13.6(j)
Additional information for medicinal products, tissues or cells, of human or animal origin, or their derivatives, or biological substances	An indication that device incorporates medicinal products, tissues or cells, of human or animal origin, or their derivatives, or biological substances. Warnings or limitations or incompatibility in the delivered substances	Not applicable	Class III	Yes	Partially Covered	23.2(e) 23.2(s)	13.6(o)
Additional information for adsorbing and locally dispersed materials	Provide main constituent or constituent responsible for achieving the principal intended action. Warnings and precautions relating to the interaction profile and products of metabolism with other devices, medicines, or substances. Contraindications, undesirable side effects and risks relating to overdose	Not applicable	Class III	Yes	No	23.2(r) 23.2(t)	New

Table 2: IFU Content Patient Information Document Activities Process Flow

d. Patient Information Document Content

Table 3 provides the patient information document content, source documents (inputs), extent of information to be included, and applicable classes. This is a new document applicable for MDR only.

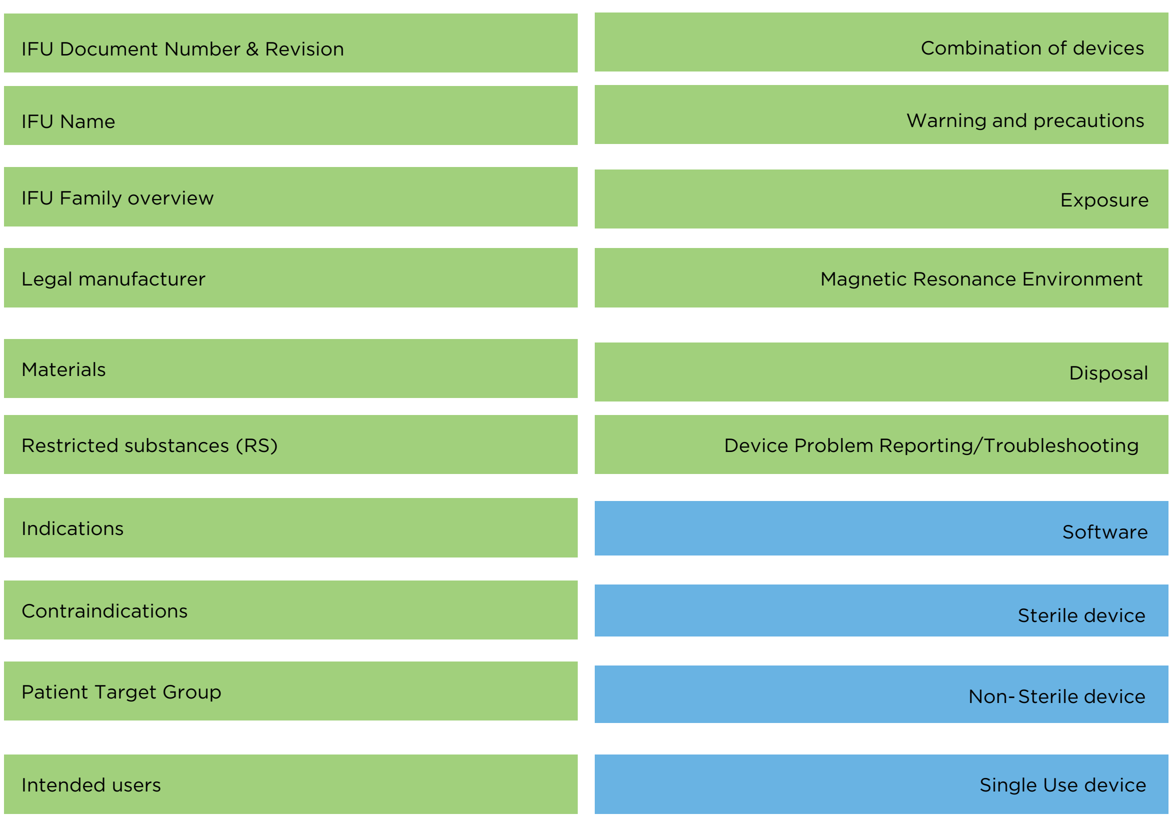
Patient information document content	Information Included	Source	MDR/MDD Applicability		MDR/MDD Reference Section	
			MDR	MDD	MDR	MDD
Patient information document number and revision	Provide issue date and revision date of the patient information document	Not applicable	Yes	No	23.4(y)	New
Identification of the device	Provide device name, serial number, lot number, the UDI, the device model, as well as the name, address, and the website of the manufacturer. This is an implant card requirement	IFU, Annex II technical documentation report, drawings	Yes	No	23.4(aa) Article 18 (a)	New
Device description	Provide short description that can be clearly understood by lay persons	IFU, Annex II technical documen-tation report	Yes	No	23.4(aa) Article 18(d)	New
Materials	List the materials and associated standards	Drawings	Yes	No	23.4(aa) Article 18(d) 23.4 (u)	New
Warnings, precautions or measures	Provide warning and precautions related to reciprocal interference with reasonably foreseeable external influences, medical examinations, or environmental conditions	MR test report, IFU, risk documents	Yes	No	23.4(aa) Article 18 (b)	New

Expected lifetime of the device and any necessary follow-up	Not applicable	Lifetime report,CER and IFU	Yes	No	23.4(aa) Article 18(c)	New
Safe use of the device for the patient	Not applicable	Not applicable	Yes	No	23.4(aa) Article 18(d) 23.4(s)	New
Updates of the information shall be made available to the patient via the website	Not applicable	Not applicable	Yes	No	23.4(aa) Article 18(a)	New

Table 3: Patient Information Document Content

e. IFU Layout

Figure 5 and 6 provides the sample IFU and patient information document layout. The heading specific to the device category is highlighted in blue. General requirements are highlighted in green.



Clinical benefits	Reusable device
Performance characteristics	Measuring Device
Residual risks and Undesirable side - effects	Radiation emitting devices
Special facilities, or special training, or particular qualifications of the device user and/or other persons	Additional Information for medicinal products, tissues or cells, of human or animal origin, or their derivatives, or biological substances
Device handling information	Additional Information for Adsorbing and Locally Dispersed Materials

Fig.5: IFU Sample Layout

f. Patient Information Document Layout

Patient information document number and revision	Warnings, precautions or measures
Identification of the device	Expected lifetime of the device and any necessary follow-up
Device description	Safe use of the device for the patient
Materials	Updates of the information shall be made available to the patient via the website

Fig.6: Patient Information Document Sample Layout

Best Practices

- HCL Technologies has subject matter experts (SMEs) specific to medical domain, and they have developed various checklists, guidelines, and process flows for MDD to MDR transition.
- The outlined IFU and patient information document process flow is simple and helps every medical device manufacturer to understand the European MDR easily and create MDR-specific IFU.

Conclusion

HCL has developed IFU and patient information document creation process in a simple and efficient way to understand the MDR IFU requirements. MDR vs MDD IFU requirements clearly provides information about the new MDR requirements, and same or similar IFU requirements between MDR vs MDD.

HCL Technologies is one of the leading medical device service providers worldwide and It has expertise in technical writing, technical review and support, IFU update, IFU translation for various major countries, including Europe, US, Japan, and China. HCL is confident that it can provide the support for IFU creation to comply with MDR.

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Boobalan Chinnathambi holds a three institute joint Master's degree in Clinical Engineering from Indian Institute of Technology Madras (IITM), Christian Medical College & Hospital, Vellore (CMC Vellore), and Sree Chitra Tirunal Institute for Medical Sciences and Technology Trivandrum (SCTIMST). He has over 7 years' experience in medical domain, having extensive experience in design quality, writing clinical evaluation reports per MED DEV 2.7.1 rev4. and ISO 14155, design requirements traceability matrix, standard evaluation, instructions for use, regulatory impact assessment, regulatory specific documentations (general safety and performance requirements checklist, essential requirements checklist, technical documentation report) for regulatory submissions. Boobalan has extensive knowledge on ISO 13485, US FDA, EU Medical Device Regulations and has hands-on experience in MDD Techfile, DHF constructions and remediation and EU MDR (745/2017) technical documentation.

Gerthruth Mary. J

Gerthruth holds a Bachelor's degree in Bio-Medical Engineering. She has more than three years of experience in the medical device industry, including research and development of electronic devices for medical applications, and preparation of technical specifications for medical devices. She joined HCL as a Regulatory Analyst over 2 years ago and has profound experience in EU MDR (2017/745) remediation and has supported gap analysis, regulatory impact assessments, creation of technical documentation, GSPR checklist, instructions for use, device labels, and declaration of conformity (DoC) for regulatory submissions.

Mathiyazhagan Muthusamy

Mathiyazhagan Muthusamy holds a Master's degree in Applied Chemistry & Chemical Engineering. He has 30+ years' experience of which he spent 20+ years in medical device manufacturing facility as the quality head, R&D, management representative for US FDA-QSR, ISO 13485, MDD (CE Mark), and certified lead auditor for the quality management system. He currently works in an engagement for a large medical devices OEM across quality, design control, technical file as per MDD, new MDR, manufacturing and sustaining services.