

# Key changes in the EN ISO 20417:2021



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# Abbreviations

Acronyms	Full form
ISO	International Organization for Standardization
BS	British Standards
N/A	Not Applicable
MDR	Medical Device Regulation
IVDR	In Vitro Diagnostic Regulation
EU	European Union
EN	European Standards
EEC	European Economic Community
IEC	International Electrotechnical Commission
USFDA	United States Food and Drug Administration
IVD	In Vitro Diagnostic
EC	European Commission
IFU	Instructions for Use
CEN	European Committee for Standardization
MDD	Medical Device Directive
eIFU	Electronic Instructions for use

# Introduction

Medical device labeling plays a crucial role in the MedTech industry. It ensures safe and effective use and provides points of reference for patients, healthcare providers and regulatory agencies.

Understanding the regulatory requirements specific to medical devices is critical, as the standards and guidelines are continually evolving and have stringent requirements.

The European standard BS EN 1041:2008+A1:2013 details the information that medical device manufacturers should supply with their products.

Recently, this standard was revised to EN ISO 20417:2021, “Medical Devices—Information to be supplied by the manufacturer.”

The revised BS EN ISO 20417:2021 specifies the general applicable requirements for labels, allowing each specific product standard or group standard to be applied to a specific medical device or group of medical devices. This revision includes the generally applicable requirements for identification and labels on a medical device or accessory, the packaging, marking of a medical device or accessory and accompanying information.

This whitepaper documents the changes and differences between BS EN 1041:2008+A1:2013 and BS EN ISO 20417:2021.

## Need for EN ISO 20417:2021

EN 1041:2008+A1:2013 covers the requirements for information to be supplied by the manufacturer for medical devices regulated by EU MDD (93/42/EEC) and AIMDD (90/385/EEC). Since, the EU MDD and AI MDD have been replaced by (EU) 2017/745, the EN ISO 20417:2021 has been published with additional requirements to comply with EU Medical Device Regulations for the safe and effective use of the medical devices or accessories and to focus more concisely on the unique requirements for a specific medical device or group of medical devices.

## Key changes in EN ISO 20417:2021

Key changes from EN 1041:2008+A1:2013 to EN ISO 20417:2021 includes:

- Scope expansion to include a broader range of medical devices and accessories
- Harmonization with international standards
- Detailed requirements for identification, labels, packaging, marking and accompanying information
- Enhanced focus on accessibility, legibility and comprehensibility of the information, ensuring it is user-friendly
- Inclusion of digital information and includes provisions for Electronic Instructions for Use (eIFU)

# Standard version and title changes

Version	Title of the standard
EN 1041:2008+A1:2013 (Existing)	Information supplied by the manufacturer of medical devices
EN ISO 20417:2021 (New)	Medical devices – Information to be supplied by the manufacturer

Note: Red – deleted items; Green – added items; Black – no change

The sections of EN ISO 20417:2021 are provided in the Figure 1 and their comparisons are provided in the following sections.

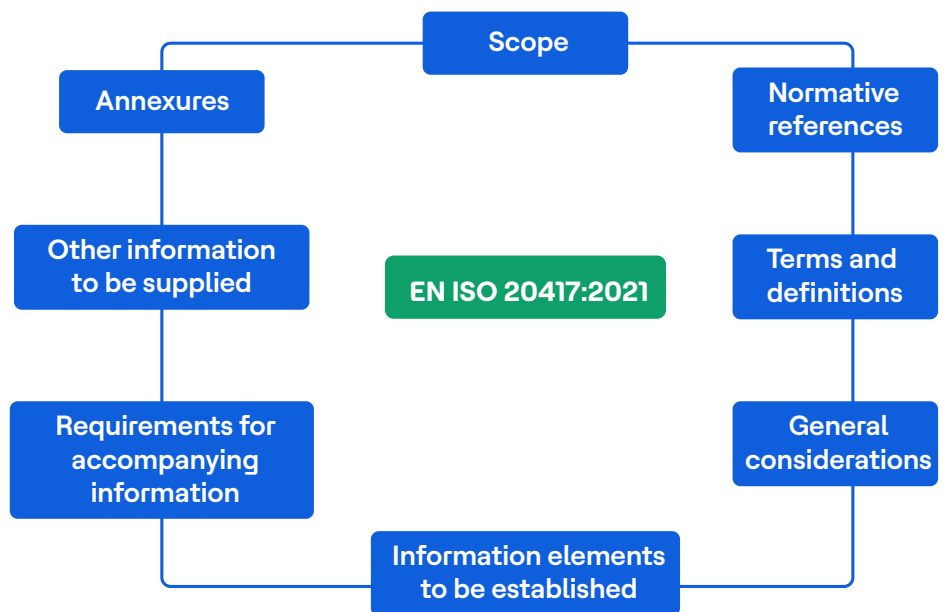


Figure 1 – Sections as per EN ISO 20417:2021

## Scope

The changes between the scope of EN 1041:2008+A1:2013 and EN ISO 20417:2021 are compared in Table 1.

**Table 1 – Comparison of scope**

EN 1041:2008+A1:2013 (Existing)	EEN ISO 20417:2021 (New)
<p>This EN specifies requirements for information to be supplied by a manufacturer for medical devices <b>regulated by Council Directive 90/385/EEC relating to active implantable medical devices and Council Directive 93/42/EEC concerning medical devices.</b></p>	<p>This document specifies the requirements for information supplied by the manufacturer for a medical device or accessory. <b>It includes the generally applicable requirements for identification and labels on a medical device or accessory, the packaging and marking of a medical device or accessory and accompanying information.</b></p>
<p>It does not specify <b>the language to be used for such information or the means by which the information is to be supplied.</b></p>	<p>This document does not specify the means by which the information is to be supplied.</p>
<p><b>It is also intended to complement the specific requirements of the cited EU Directives on medical devices by guiding how certain requirements can be met. If a manufacturer follows these means, they will provide a presumption of conformity with the relevant Essential Requirements regarding information to be supplied. This standard does not cover information requirements for in vitro diagnostic medical devices, which are covered by other labelling standards.</b></p>	<p><b>Specific requirements of medical device product standards or group standards take precedence over requirements of this document.</b></p>
<p><b>Note: Red – deleted requirements; Green – added requirements; Black – no change</b></p>	

## Normative references

The changes between the normative references of EN 1041:2008+A1:2013 and EN ISO 20417:2021 are compared in Table 2.

**Table 2 – Comparison of normative references**

EN 1041:2008+A1:2013 (Existing)	EN ISO 20417:2021 (New)
<p>The following documents, <b>in whole or in part, are normatively referenced in this document and are indispensable for its application.</b> For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies</p>	<p>The following documents <b>are referred to in the text in such a way that some or all of their content constitutes requirements of this document.</b> For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.                      ISO 3166 1, Codes for the representation of names of countries and their subdivisions – Part 1: Country codes</p>
<p>EN ISO 3166-1, Codes for the representation of names of countries and their subdivisions Part 1: .</p> <p>Country codes (ISO 3166-1:2006) ISO 639-1, Codes for the representation of names of languages Part 1: Alpha-2 Code ISO 1000, SI units and recommendations for the use of their multiples and of certain other units ISO 8601, Data elements and interchange formats Information interchange Representation of dates and times CEN/TR 15133, Nomenclature Collective terms and codes for groups of medical devices</p>	<p>ISO 3864 1:2011, Graphical symbols – Safety colors and safety signs – Part 1: Design principles for safety signs and safety markings                      ISO 7000, Graphical symbols for use on equipment – Registered symbols                      ISO 7010:2019, Graphical symbols – Safety colors and safety signs – Registered safety signs                      ISO 8601 1, Date and time – Representations for information interchange – Part 1: Basic rules                      ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes                      ISO 14971:2019, Medical devices – Application of risk management to medical devices                      ISO 15223 1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements                      ISO 16142 1:2016, Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards                      IEC 60417, (database), Graphical symbols for use on equipment                      Medical devices – Part 1: Application of the usability engineering process to medical devices</p>
	<p>ISO 80000 1, Quantities and units – Part 1: General</p>
<p>Note: <b>Red – deleted requirements;</b> <b>Green – added requirements;</b> <b>Black – no change</b></p>	

# Terms and definitions

The changes between the terms and definitions of **EN 1041:2008+A1:2013** and **EN ISO 20417:2021** are compared in Table 3 and Figure 2.

Only clause titles are discussed and the contents are not discussed in this section, but the contents are verified for the any modification/change.

S. No	EN 1041:2008+A1:2013 (Existing)		EN ISO 20417:2021 (New)		New / Modified / Deleted / No change
	Clause	Terms and definition	Clause	Terms and definition	
1	-	-	3.1	Accessory	New
2	-	-	3.2	Accompanying information	New
3	-	-	3.3	Catalogue number Commercial product name Commercial product code	New
4	-	-	3.4	Clearly legible Easily legible	New
5	-	-	3.5	Distributor	New
6	-	-	3.6	Electronic documentation	New
7	-	-	3.7	Expected lifetime Expected service life	New
8	-	-	3.8	Importer	New
9	-	-	3.9	Information for safety	New
10	3.4	Information supplied by the manufacturer	3.10	Information supplied by the manufacturer	Modified
11	-	-	3.11	Instructions for use / IFU / Package insert	New
12	-	-	3.12	Label	New
13	-	-	3.13	Lay / Lay person	New
14	3.1	Batch / lot	3.14	Lot / Batch	Modified
15	3.2	Batch code; lot number; batch number; lot code	3.15	Lot number / Batch code / Batch number / Lot code	Modified
16	3.3	Alternative labelling	-	-	Deleted
17	3.5	Medical device	-	-	Deleted

Table 3 – Comparison of terms and definitions

S. No	EN 1041:2008+A1:2013 (Existing)		EN ISO 20417:2021 (New)		New / Modified / Deleted / No change
	Clause	Terms and definition	Clause	Terms and definition	
18	3.6	User	-	-	Deleted
19	-	-	3.16	Marking	New
20	-	-	3.17	Model number / Model	New
21	-	-	3.18	Multiple patient multiple use	New
22	-	-	3.19	Pictogram	New
23	-	-	3.20	Processing	New
24	-	-	3.21	Safety sign	New
25	-	-	3.22	Serial number	New
26	-	-	3.23	Service personnel	New
27	-	-	3.24	Shelf-life	New
28	-	-	3.25	Single patient multiple use	New
29	-	-	3.26	Single use / Do not reuse / Use only once	New
30	-	-	3.27	Stability	New
31	-	-	3.28	Sterile	New
32	-	-	3.29	Symbol	New
33	-	-	3.30	Technical description	New

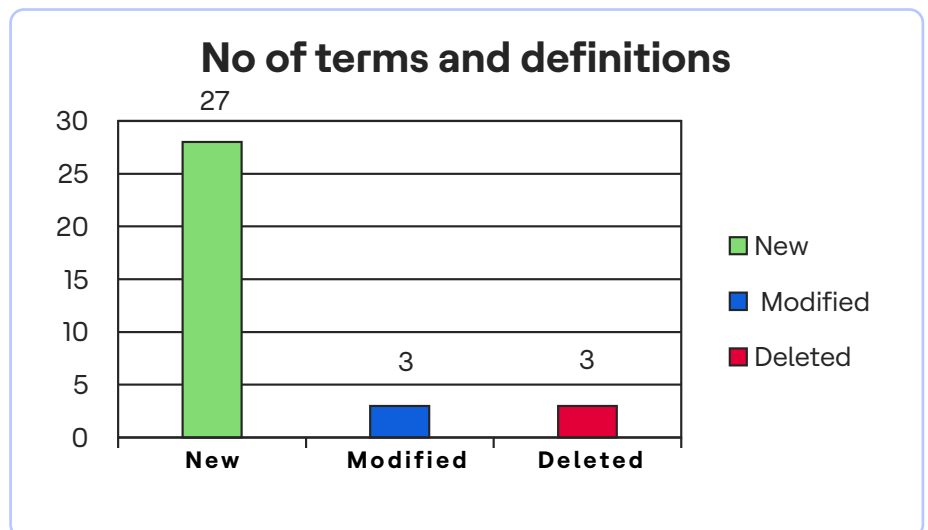


Figure 2 - Comparison of terms and definitions

## Requirements

The changes between the requirements of **EN 1041:2008+A1:2013** and **EN ISO 20417:2021** are compared in Table 4, 5 and Figure 3.

EN ISO 20417:2021 covers the following sections from the standard and is compared with EN 1041:2008+A1:2013

- Section 4 – General considerations
- Section 5 – Information elements to established
- Section 6 – Requirements for accompanying information
- Section 7 – Other information to be supplied

Deleted, modified and no change requirements are captured in table 4.

New requirements are captured in Table 5.

Only clause titles are discussed and the contents are not discussed in this section, but the contents are verified for any modification or change.

<b>Table 4 – Deleted, modified and no change requirements</b>			
<b>S. No</b>	<b>EN 1041: 2008+A1:2013 (Existing)</b>	<b>EN ISO 20417:2021 (New)</b>	<b>New / Modified / Deleted / No change</b>
	<b>Clause</b>	<b>Clause</b>	
1.	4.1 General	4. General considerations	Modified
2.	4.2 Units, symbols and colors	5.1 Units of measurement	Modified
		5.2 Graphical information	Modified
3.	4.3 Language and country identifiers	5.3 Language and country identifiers	Modified
4.	4.4 Dates	5.4 Dates	Modified
5.	4.5 Device nomenclature	-	Modified
6.	4.5.2 Device common terms	-	Deleted
7.	4.5.3 Batch code; lot number; batch number; lot code	5.9 Production controls	Deleted
8.	5.1 General 5.1.1 Safe and effective use of the device	4.c), d), e) General considerations	No change
9.	5.1.2 Address required under medical devices directives	6.1.2) Identification of the manufacturer	No change
		5.5) Full address	Deleted
10.	5.2.1 Applicability	-	Modified
11.	5.2.2 Accessibility	4.e) General considerations	Modified
12.	5.2.3 Legibility	6.3) Legibility of the label	Modified
13.	5.2.4 Availability	6.4) Durability of markings	Deleted
14.	5.2.5 Security	-	Deleted
15.	5.2.6 Changes to information provided	-	Deleted
16.	6. Documentation	-	Deleted

**Table 5 – New requirements**

Table 5 – New requirements		
S. No	EN ISO 20417:2021	
	Section	Clause
1	4. General considerations	(b) Residual risk
2	5. Information elements to be established	5.6 Commercial product name
		5.7 Model number
		5.8 Catalogue number
		5.10 Unique device identifier
		5.11 Type of use/reuse
		5.12 Sterile
	6. Requirements for accompanying information	
3.	6.1. Requirements for information to be supplied on the label	6.1.1 Minimum requirements for the label
		6.1.3 identification of medical device or accessory requirements
		6.1.4 Other label
		6.1.5 Consult instruction for use
		6.1.6 safety signs
4.	6.2. Identification requirements for detachable components of a medical device or accessory	N/A
5.	6.5 Information to be provided on the packaging	6.5.1 General information
		6.5.2 Packaging for the lay user
		6.5.3 Special conditions indicated on the packaging
6.	6. Requirements for information in the instructions for use and technical description	6.6.1 General
		6.6.2 Requirements for instructions for use
		6.6.3 Additional requirements for the instructions for use for a lay user
		6.6.4 Requirements for technical description
		6.6.5 Requirements for e-documentation
7.	7. Other information that is required to be supplied with the medical device or accessory	7.1 Importer
		7.2 Distributor
		7.3 Repackaging
		7.4 Translation
		7.5 Regulatory identification

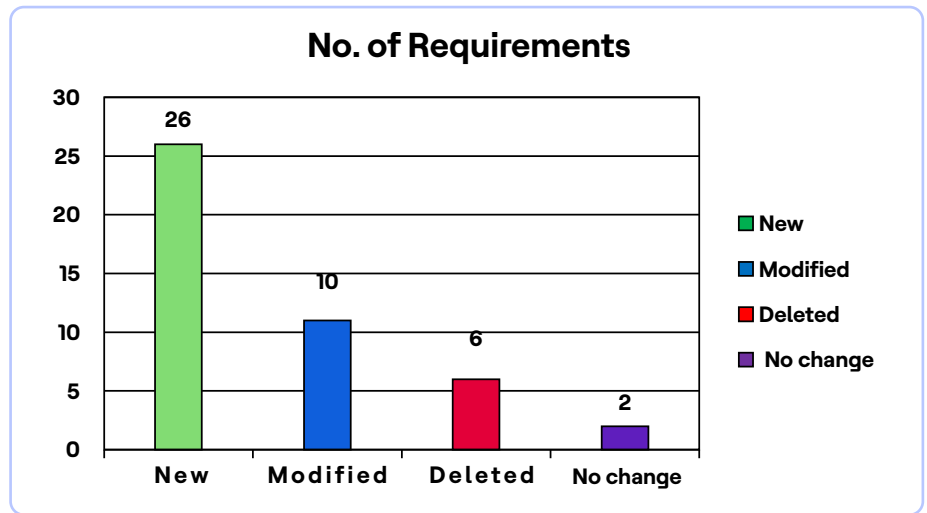


Figure 3 - Comparison of requirements

## Annexures

The changes between the annexures of EN 1041:2008+A1:2013 and EN ISO 20417:2021 are compared in Table 6 and Figure 4.

Note: Only clause titles are discussed and the contents are not discussed in this section, but the contents are verified for the any modification/ change.

S. No	EN 1041: 2008+A1:2013 (Existing)	EN ISO 20417:2021 (New)	Remarks	New / Modified / Deleted / No change
	Annex	Annex		
1.	<p><b>Annex A</b> Requirements and guidance for Directives 93/42/EEC and 90/385/EEC, as amended</p> <p>A.1 Requirements and guidance for medical devices (Directive 93/42/EEC)</p> <p>A.2 Requirements and guidance for active implantable medical devices (Directive 90/385/EEC)</p> <p><b>Annex ZA</b> Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EC</p>	<p><b>Annex D</b> <b>Cross reference between the document and the requirements considered</b></p>	<p><b>Annexure D</b> refers the cross reference between 93/42/EEC, 90/385/EEC, 98/79/EC and (EU) 2017/745 and (EU) 2017/746.</p>	Modified

Table 6 – Comparison of annexures

S. No	2008+A1:2013 (Existing)	EN ISO 20417:2021 (New)	Remarks	New / Modified / Deleted / No change
	Annex	Annex		
	<b>Annex ZB</b> <b>Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EC</b>			Modified
2.	<b>Annex B Guidance on alternative labelling for instructions for use (IFU)</b>  B.1 Guidance on alternative labelling for medical devices (Directive 93/42/EEC) B.2 Guidance on alternative labelling for active implantable medical devices (Directive 90/385/EEC)	-	Requirements for alternative labelling (e-documentation are referred in 6.6.5 and 6.1.3 d) 1))  <b>Requirements 6.6.5</b> Requirements for e-documentation <b>6.1.3 d) 1)</b> indication of electronic instructions for use	Deleted
3.	-	<b>Annex A</b> Particular guidance and rationale	-	New
4	-	<b>Annex B</b> Example test method for assessing clearly legible requirements	-	New
5	-	<b>Annex C</b> Example test method for assessing durability	-	New

Table 6 – Comparison of annexures				
S. No	EN 1041:2008 +A1:2013 (Existing)	EN ISO 20417:2021 (New)	Remarks	New / Modified / Deleted / No change
	Annex	Annex		
6	-	<b>Annex E</b> Reference to the IMDRF essential principles and labelling guidance's	-	New
7	-	<b>Annex F</b> Reference to the essential principles	-	New
8	-	<b>Annex G</b> Reference to the general safety and performance requirements for medical devices	-	New
9	-	<b>Annex H</b> Reference to the general safety and performance requirements for IVD medical devices	-	New
10	-	<b>Annex I</b> Terminology – Alphabetized index of defined terms	-	New

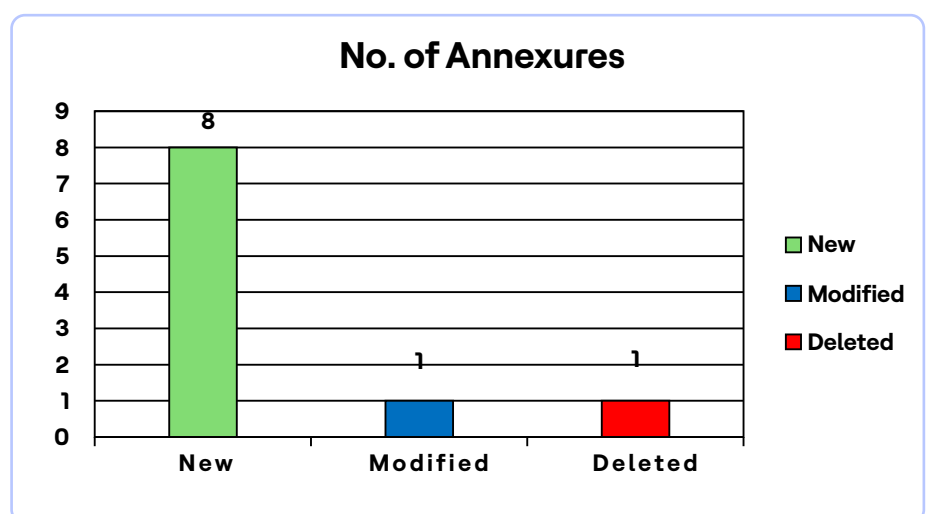


Figure 4 - Comparison of annexures

# Different formats of information supplied by the manufacturer

The manufacturer can supply information related to the identification and use of a medical device or accessory in multiple formats to ensure its safe and effective use, as mentioned in Figure 5.

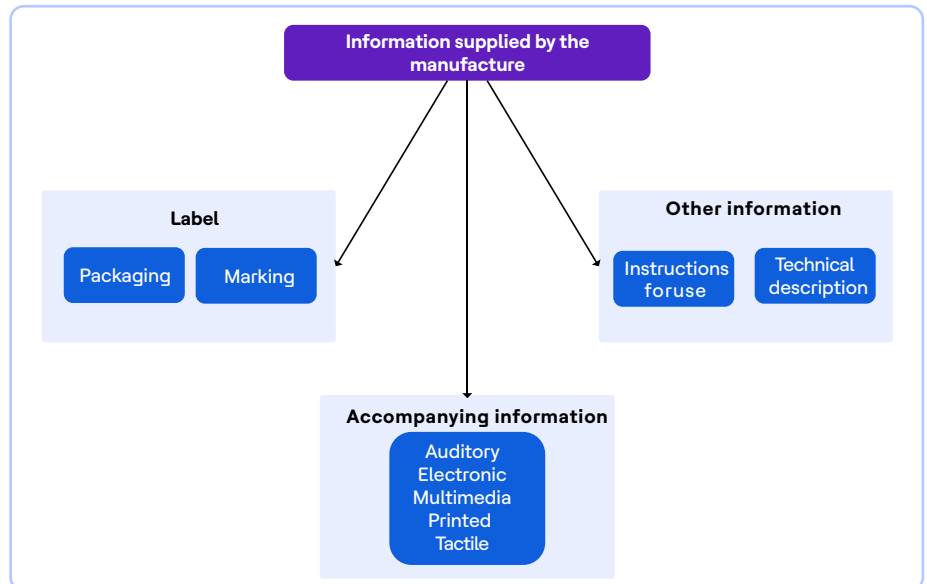


Figure 5 – Information supplied by the manufacturer

## Conclusion

The “EN ISO 20417-2021 – Medical Device - Information to be supplied by the manufacturer” standard introduces new requirements and annexures aligned with European Medical Device Regulations. In addition, it specifies requirements for medical device labels, label legibility, durability of the markings, packaging, safety signs, instructions for use, technical descriptions, e-documentation and regulatory identifications. These updates underscore the need for manufacturers to stay current with regulations to ensure compliance and maintain high safety and performance standards.

HCLTech brings over two decades of experience delivering end-to-end solutions for medical device manufacturers, ensuring compliance with global regulatory standards. The Labeling CoE team at HCLTech offers comprehensive medical device labeling solutions that address global and regional regulatory requirements, including translation services and enterprise labeling needs. The team comprises skilled graphic designers, labeling engineers, proofreaders, technical writers and subject matter experts, with extensive expertise in advanced labeling solutions and technologies. In response to evolving regulatory labeling requirements, HCLTech has conducted a thorough investigation, leading to a detailed

gap analysis, comparative analysis, process flows, checklists, redlining and label/artwork creation and development. They specialize in designing and developing IFUs and eIFUs, along with proofreading and transition planning. These proactive efforts are designed to save customers valuable time and resources, enabling a smoother path to market and supporting the launch of innovative, sustainable medical products.

They also specialize in automation and GenAI-based solutions for labeling, design and development of Instructions for Use (IFUs) and electronic IFUs (eIFUs), proofreading and transition planning. HCLTech proprietary labeling solutions include Reline Automation, Data extraction engine, Artwork Sustenance and AI label Analyzer.

## References

- EN ISO 20417:2021 Medical Devices – Information to be supplied by the manufacturer.
- EN 1041:2008+A1:2013 – Information supplied by the manufacturer of medical devices.

# Author information



## **Ajith A**

Ajith holds a Bachelor's in Printing and Packaging Technology from Anna University. He is an expert in the design and development of medical device packaging and labelling, related standard gap assessments, redlining and remediation activities. He is currently handling Medical Device Packaging and labelling for EU MDR 745/2017, USFDA and EU IVDR 746/2017 at HCLTech, Chennai.

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