[Organization logo]

[Organization name]

Commented [AES1]: All fields in this document marked by square brackets [ ] must be filled in.

PROCEDURE FOR LABELING

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [AES2]: The document coding system should be in line with the organization's existing system for document coding; in case such a system is not in place, this line may be deleted.

Distribution list

Commented [AES3]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

Copy no.	Distributed to	Date	Signature	Returned	
				Date	Signature

Change history

Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

Table of contents

1. Purpose, scope and users

The purpose of this Procedure is to define how the labeling of medical products is carried out in [organization name], and how translations of labels and instructions for use (IFU) into other languages are managed.

Users of this document are persons responsible for quality control, production, and warehousing in [organization name].

2. Reference documents

- ISO 14971:2019
- ISO 15223-1:2021
- MDR 2017/745, article 10(11) and Annex I – Chapter III
- [other applicable standards]
- Procedure for Purchasing and Evaluation of Suppliers
- Procedure for UDI System
- Procedure for Identification and Traceability

3. Labels

[Job title] is responsible for proper design of the label for the medical device and for marking the medical device in compliance with both MDR, ISO 15223, and [other applicable standards].

When designing the label, [job title] must consider the following:

- Label medium
- Label format
- [illegible]
- [illegible]

[illegible]

3.1. Labeling and packaging design and validation

[Job title] is responsible for ensuring that labels, and their artwork, are developed in the product design phase.

[Job title] is responsible for validating the packaging of the medical device by testing it under actual or simulated conditions of distribution, storage, and use. [illegible]

Commented [AES4]: Include the name of your organization.

Commented [AES5]: Include the name of your organization.

Commented [AES6]: Delete this if your organization does not need to be compliant with MDR.

You can find the full text of the MDR on the following link: https://advisera.com/13485academy/mdr/

Commented [AES7]: Add other standards applicable to your organization, e.g., IEC 60601, or delete if there are no other applicable standards.

Commented [AES8]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "11_Purchasing_and_Evaluation_of_Suppliers".

Commented [AES9]: E.g., Production Manager

Commented [AES10]: Write any other applicable standards.

[illegible]

Commented [AES11]: E.g., Production Manager

Commented [AES12]: E.g., Is it on paper, on the medical [illegible]

Commented [AES13]: You can find the entire text of Annex I on the following link:

[illegible]

Commented [AES14]: Letters and symbols must be of proper [illegible]

Commented [AES15]: E.g., Production Manager

Commented [AES16]: E.g., Production Manager, Quality [illegible]

Commented [AES17]: E.g., Production Manager, Quality [illegible]

Commented [AES18]: E.g., Production Manager, Quality [illegible]

Commented [AES19]: You can delete this paragraph if your medical device is not sterile or packaging is not designed to meet [illegible]

Labels are manufactured by [organization name]. [Job title] is responsible for the inspection of manufactured labels.

[Job title] is responsible for the inspection of incoming purchased labels in accordance with the Procedure for Purchasing and Evaluation of Suppliers.

While performing the labeling inspection, [job title] must verify the following:

- The labels are printed using approved and most recently updated label artwork/specifications,
- The materials and printing comply with specifications, and
- Correct control numbers are used.

4. Packaging levels

[Organization name] has [number] levels of packaging. [Job title] is responsible for preparing the appropriate label for each packaging level. In accordance with the applicable standards listed in section 2 of this document, and in accordance with the Procedure for UDI System and the Procedure for Identification and Traceability.

[Job title] must use the following symbols on any level of packaging or on IFU:

Symbol reference number	Meaning / Description	Symbol

4.1. Primary packaging

[Job title] must prepare a graphical design of the label for the primary packaging level and send it to the [manufacturing department/manufacturer].

4.2. Secondary packaging

[Job title] must prepare a graphical design of the label for the secondary packaging level and send it to the [manufacturing department/manufacturer].

4.3. Tertiary packaging

[Job title] must prepare a graphical design of the label for the tertiary packaging level and send it to the [manufacturing department/manufacturer].

5. Instructions for use (IFU)

Commented [AES20]: Include the name of your organization.

Commented [AES21]: Delete this if your organization does not

Commented [AES22]: E.g., Production Manager, Quality

Commented [AES23]: Delete this if your organization

Commented [AES24]: Include the name of your organization.

Commented [AES25]: Include the number of packaging levels

Commented [AES26]: E.g., Production Manager, Quality

Commented [AES27]: Include here the symbol reference

Commented [AES28]: Primary packaging is the packaging in direct contact with the product itself and is sometimes referred to

Commented [AES29]: E.g., Person responsible for technical

Commented [AES30]: Use the one that applies to your organization's practices.

Commented [AES31]: Secondary packaging's main purpose is for branding display and logistical purposes.

Commented [AES32]: E.g., Person responsible for technical

Commented [AES33]: Use the one that applies to your organization's practices.

Commented [AES34]: Tertiary packaging facilitates the

Commented [AES35]: If you do not have tertiary packaging

Commented [AES36]: E.g., Person responsible for technical

Commented [AES37]: Use the one that applies to your

Commented [AES38]: According to the MDR 2017/745, Annex

[Job title] is responsible for ensuring that IFU are prepared with all necessary elements and symbols stated on the label as described in Annex I – General safety and performance requirements, clause 23.4.

[redacted]

[redacted]

6. Translation procedure

[Job title] must contact an authorized translation institution and organize the translation of the labels and IFU in at least one official language of the European Union, or in the language of the Member Country where the product is registered.

[redacted]

[job title]
[name]

_____
[signature]

Commented [AES39]: E.g., Production Manager, Quality [redacted]

Commented [AES40]: You can find the entire text of Annex I on the following link: [redacted]

Commented [AES41]: E.g., Production Manager, Quality [redacted]

Commented [AES42]: Include the name of your organization.

Commented [AES43]: Delete this paragraph if IFU are not [redacted]

Commented [AES44]: E.g., Production Manager, Quality [redacted]

Commented [AES45]: Delete this paragraph if IFU are not [redacted]

Commented [AES46]: E.g., Production Manager, Quality [redacted]

Commented [AES47]: E.g., Production Manager, Quality [redacted]

Commented [AES48]: Adapt to the organization's practice.

Commented [AES49]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.