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PROCEDURE FOR LABELING

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# 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].

# 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

# 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
* Information to be included on the label, which must be aligned with the requirements from Annex I, clauses 23.1 and 23.2 of the MDR 2017/745
* Legibility

[Job title] must ensure that the place where the label is attached, and the instructions included on the label, are appropriate given the technical knowledge, experience, and education, of the intended user(s).

## Labeling and packaging design and validation

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

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