

Labelling

Correct labelling is an important aspect of the device. Examples of labelling:

- User Manual
- Service Manual
- Quick reference card
- Shipping labels (if applicable)
- Package labels (if applicable)
- Software User Interface
- Marketing advertisements
- Website with product info
- Sales literature
- TV, Newspaper, radio advertisements

Labelling errors, i.e., making (clinical) claims that are not part of the CE approval (falsely labelling) or omitting required information can lead to serious problems, e.g. produce recalls, civil and criminal penalties.