Minimum Outline for Medical Device Manual

About this Outline

This outline is intended for commercially produced medical devices which must meet EU regulations.

Source of this Outline

Helpful Engineering - Google Docs:
https://docs.google.com/document/d/1QE6FUh9OGGN3Aq6274AcszcRhWEVMO4A4DqnUa7vj4k/edit?usp=sharing

https://instrktiv.com/en/ifu-medical-devices/

Basic info

- The (trade) name of the medical device;
- The (trade) name (or registered trade mark) and the address of the manufacturer;
- The date of issue of the instructions for use, or revision dates and information about where to find the latest revision of the instructions for use;

Comment [1]: very important as I expect everything to be updated regularly

Sterilisation

- If the medical device is supplied sterile, an indication of its sterile state and the sterilisation method;
- If applicable, instructions for when a sterile packaging is damaged or accidently opened before use;
- Instructions for sterilisation (only applies to medical devices that are supplied non-sterile and should be sterilised before use);

Purpose and usage of the device

- The intended purpose, including any contra-indications, a specification of indications, the patient target group(s), and of the intended users;
- Training or qualification requirements and information about the device user and/or other persons and information about special facilities;
- Medical devices intended for use together with other devices and/or general purpose equipment must include information to identify such devices or equipment so they can be safely used together and/or information about any known restrictions to combinations of devices and equipment;
- A description of when the user should consult a healthcare professional (in case the device is intended for use by lay persons)
- Specifications the user requires to use the medical device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it must be given;

Single use

- If applicable, a statement when the medical device is intended for single use;
- Devices intended for single use only must contain information about the risks if the device were to be re-used;

Re-usable

- For reusable devices, information on the processes for cleaning, disinfection, packaging and, if applicable, the validated method of re-sterilisation as determined by the country where the product is sold and used. When there are, for example, signs of degradation or in case the maximum number of allowable reuses has been reached, it must be mentioned that the device shall not be used anymore;
- If applicable, a statement that a medical device can be reused when it is reconditioned under the responsibility of the manufacturer;

Benefits, performance

- If applicable, the clinical benefits that can be expected;
- If applicable, links to the summary of safety and clinical performance (see article 32 of the Regulation);
- The performance characteristics of the medical device;
- For groups of products without an intended medical purpose that are listed in Annex XVI of the Regulation (such as contact lenses and liposuction equipment) information regarding the absence of a clinical benefit and the risks related to use of the device.
- For devices that incorporate electronic programmable systems (including software, or software that are devices in themselves) the minimum requirements concerning hardware, IT networks characteristics and IT security measures necessary to run the software as intended must be given.

Storing, handling, installing

- Storing and handling information;
- Information that is needed to verify if the medical device is properly installed and ready to be used as intended. This information must include, where relevant, instructions regarding maintenance, cleaning/disinfection, replacement of consumables, calibration and how to eliminate risks;
- Detailed information about all preparatory treatments or handling of the device before it is ready for use or during its use (e.g. sterilisation, calibration, final assembly). Also, the levels of disinfection required and the available methods for achieving these levels must be included.

Warnings

- Any residual risks, contra-indications and any undesirable side-effects. This must include information to be conveyed to the patient.

- Any relevant warnings, precautions, contraindications, measures to be taken and limitations of use regarding the device.
- All relevant warnings and precautions when substances are intended to be introduced into the human body;
- For devices emitting radiation for medical purposes, detailed information about the nature, type and the intensity and distribution of the emitted radiation, and information about how to protect users, patients or other persons shall be given;

Disposal

- Detailed instructions for the safe disposal of the medical device, its accessories and the consumables.

IF the device contains or incorporates a medicinal substance

- If applicable, an indication that the medical device contains or incorporates a medicinal substance (including a human blood or plasma derivative), tissues or cells (or their derivatives of human origin), or tissues or cells of animal origin (or their derivatives)
- If applicable, information about substances that are subject to label requirements (according to section 10.4.5. of the Regulation);
- In the case of medical devices that are composed of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by, or locally dispersed in the human body, the overall qualitative composition of the device, including quantitative information on the main constituent(s) responsible for achieving the principal intended action;

Misc

- If applicable, information allowing the healthcare professional to verify if the medical device is suitable to work with.

- If applicable, information allowing the healthcare professional to select the correct corresponding software and accessories;
- A notice that users and/or patients must report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the country in which the user and/or patient is established;

Implantable devices

- For implantable devices, the overall qualitative and quantitative information about the materials and substances to which patients can be exposed;
- For implanted devices, information to identify the device (name, serial number etc), warnings and precautions regarding reciprocal interference, medical examinations or environmental conditions, information about the expected lifetime and any other information to ensure safe use of the device.