An Introduction to Rules and Regulations

Every day numerous medical devices are used in health care facilities and elsewhere all over Sweden. Most devices are quite simple, while others are complex and combine different technologies.

Defects or disturbances in the functions of medical devices may expose patients to serious risks. This is particularly true for devices which transfer energy or pharmaceuticals to patients, e.g. infusion pumps, or devices which sustain or support vital functions, e.g. pacemakers.

Nonetheless the safety standards must be high for all medical devices. The devices shall be safe and reliable and well suited for their intended purposes. Sweden has brought its legislation in line with the safety requirements in force within the EU concerning testing, certification and labelling of medical devices.

One procedure for EEA-countries

The purpose of EU’s product directives is to ensure safety and performance of the devices and at the same time enable free trade. The medical device directives different parts have been transposed to a Swedish Act (SFS 1993:584), Ordinance (SFS 1993:876) and Regulations LVFS 2001:5, LVFS 2003:11 and LVFS 2001:7 from Medical Products Agency, respectively. The implementation is almost a word by word transformation of the directives texts.

According to the Swedish Medical Devices Act (1993:584) and the Medical Devices Ordinance (1993:876) a medical device shall achieve its intended purpose as designated by the manufacturer and involve no unacceptable risk to patients, staff or third parties.

The Act and the Ordinance have been adopted to the European Community Medical Devices Directives that successively have been introduced into the European Economic Area, EEA, comprising the 25 EU-countries, Iceland, Liechtenstein and Norway. The provisions of the Directives have been introduced into the Medical Products Agency statutes book as LVFS 2001:5 (The Active Implantable Medical Devices Directive 90/385/EEC), LVFS 2003:11 (The Medical Devices Directive 93/42/EEC) and LVFS 2001:7 (The In-Vitro Diagnostic Medical Devices Directive 98/79/EG).

In respect of active implantable medical devices (which are subject to LVFS 2001:5) this means that with effect from 1 January 1995 these devices must be certified, i.e. have been assessed by a Notified Body, before being placed on the market. Certification of medical devices subject to LVFS 2003:11 began on 1 January 1995 and has been mandatory from June 14, 1998. These devices are grouped into classes (I, IIa, IIb and III) determining the requirements for certification. The certification requirements for in-vitro diagnostic medical devices is mandatory from December 8, 2003. Devices which have undergone certification will be provided with the CE-mark.

It is important to study the definitions (compare the Act) of the medical device and the manufacturer, respectively. The intended use and the mechanisms of action of the device, not the construction or the user, controls if the device becomes a medical device. The “manufacturer”, in this context, is the (legal) manufacturer who has the responsibility for the product safety.

Medical Products Agency is the Competent Authority in Sweden

The role of Medical Products Agency is determined by the Medical Devices Act and Ordinance. The Agency’s responsibilities include putting statutory regulations into place and monitoring their effectiveness through market control.

Basic requirements

Definition: "Medical device" means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Each medical device placed on the market must comply with the requirements in the Medical Devices Act, irrespectively of how the device is to be used and risks associated with its use.

A device is considered suitable if, when used as intended, it achieves the performance intended by the manufacturer and meets high standards for the protection of life, personal safety and health of patients and others.
Essential requirements

The Essential Requirements are an extension of the basic requirements. In brief the essential requirements state that safety and performance must be documented, and that potential side effects and risks must be described. The manufacturer must also have performed an analysis, showing that the benefits of the device are considered to outweigh the side effects.

Information concerning use, intended purpose, risks etc. shall be stated on the device or, if this is not possible, in accompanying instructions.

Something which manufacturers in particular have to observe, is that labelling and instructions for use (users manual, display, voice etc.) according to paragraph 4 in the Regulations (LVFS 2001:5, LVFS 2003:11 and LVFS 2001:7 respectively) shall be written in Swedish. This is irrespective of the device being used by a patient or by trained staff or if the device is used in a hospital or in an accommodation. Service manuals might be in English.

The manufacturer´s internal control documentation in combination with a technical file and a declaration of conformity asserting that the device complies with the requirements, will normally be sufficient.

Third party assessment

For certain devices it is necessary that an assessment is carried out by a third party, a so called Notified Body, to demonstrate that the device complies with the requirements.

A Notified Body is an independent testing and/or certification organisation which has been deemed to possess sufficient competence and quality to evaluate the conformity of goods and services. Swedish Notified Bodies that have been designated by SWEDAC (Swedish Board for Accreditation and Conformity Assessment) fulfil these requirements.

Each EEA country sends a list of the Notified Bodies under its jurisdiction to the EU Commission, and their names are published in the Official Journal of the European Communities, under the relevant directive.

It is sufficient for the manufacturer to carry out a conformity assessment on his devices in one country in order to gain access to the entire EEA market.

Standards

Technical specifications are to be found in standards. The so called Harmonised Standards have been developed by the western European standardisation organisations CEN, CENELEC and ETSI on mandates of the EU Commission. Harmonised Standards are presumed to comply with the Essential Requirements in the directives. Parts of the European Pharmacopoeia also fulfills this presumption of conformity. The standards are of importance for the design, manufacturing and procurement.