

Medical devices

The term 'medical devices' covers more than half a million widely different products, which are used to diagnose, treat or relieve illnesses.

Devices used in hospitals and aids used in nursing homes, in home care services and private homes are medical devices.

Duty to report

Device malfunction can have serious consequences, and device manufacturers as well as healthcare professionals have a duty to report all incidents and accidents caused by device malfunction to the Danish Medicines Agency.

Incident reporting improves safety

The knowledge that the Danish Medicines Agency acquires from the reports makes it possible to prevent the occurrence of incidents, thereby increasing the safety for users.

The device manufacturers and healthcare professionals identify the cause of the incident in interaction with the Danish Medicines Agency.

Examples of medical devices:

- syringes
- surgical instruments
- hospital beds
- pacemakers
- hip implants
- crutches
- condoms
- diagnostic kits, e.g. blood glucose tests
- dentures
- glasses
- patches
- pregnancy tests.

The Danish Medicines Agency's objectives

- To prevent incidents caused by medical device failure
- To contribute to the development of medical devices of high safety and performance.

Healthcare professionals are notified directly about any warnings, for instance relating to the instructions for use. If necessary, the device will be recalled.

Supervision of device manufacturers

Medical devices are not approved, but the Danish Medicines Agency is responsible for many other tasks that aim to improve patient safety.

We supervise Danish medical device manufacturers, and we also monitor the notified bodies in Denmark that check the safety and performance documentation for high-risk products (e.g. x-ray scanners, bone cement and radiation therapy equipment). In addition, we register manufacturers responsible for low-risk products (wheelchairs, glasses etc.).

International perspectives

Legislation on medical devices applies to all EU member states. The authorities of all EU member states are responsible for supervising the safety of the products on the entire European market.

We therefore participate actively in the development of a comprehensive European and international collaboration comprising:

- exchange of information on incidents
- monitoring of the notified bodies
- clinical investigations of medical devices



- development of market surveillance
- preparation of legislation.

Online guidelines and forms

At www.medicaldevices.dk, device manufacturers and healthcare professionals can find guidelines and forms for reporting incidents and accidents with medical devices.

Manufacturers can also find information about registration, export certificates and labelling requirements for devices.

Other content on the website

- Legislative framework
- EU directives
- Information from the Danish Medicines Agency
- Guidance documents from the European Commission.

Write to us

If you have any questions concerning medical devices, please send them to: med-udstyr@dkma.dk.

Legislative framework

Manufacturers of medical devices are responsible for:

- compliance with safety and performance requirements
- documentation for compliance with the requirements
- drawing up of labelling and instructions for use
- assessing the device by a notified body.

The Danish Medicines Agency

administers the legislation, and among its duties are:

- registration and handling of incidents with medical devices
- registration of manufacturers
- supervision of compliance with legislation
- monitoring of notified bodies
- assessment of applications for clinical investigations of medical devices.

