



# Medical Device Regulations: Global Overview and Guiding Principles

*World Health Organization*

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## **Medical Device Regulations: Global Overview and Guiding Principles** World Health Organization

Medical devices and equipment are a vital component of patient care. From a simple tongue depressor to a sophisticated haemodialysis machine, medical devices are needed at every level of the health service. Yet many health services continue to lack information and financial resources to acquire the devices they really need, i.e. those that will address the specific disease burden in their country. Effective implementation of a National Regulatory Authority is a first step towards the cost-effective management of medical devices that meet international quality and safety standards, throughout their entire life span, from conception to disposal.

This publication offers countries a framework within which they can plan - or improve - their regulatory system for medical devices. Governments are particularly encouraged to take advantage of the extensive work undertaken over the last ten years by national and regional bodies to harmonize regulations on medical devices. Countries can also adopt the device approvals of the advanced regulatory systems. These two approaches alone can enable national health authorities to redirect scarce resources towards locally assessed needs, such as vendor and device registration, training, surveillance and information exchange systems on medical devices in use.

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