MEDICAL TECHNOLOGIES EVALUATION PROGRAMME

DEFINITION OF TECHNOLOGIES WHICH FALL WITHIN THE REMIT OF THE PROGRAMME

The Medical Technologies Evaluation Programme identifies medical technologies that have the potential to offer substantial benefit to patients and/or to the NHS and are likely to be adopted more consistently and more rapidly if NICE develops guidance on them. In order for a technology to be considered by the programme it must fall within the following definitions of a medical device.

Definitions of medical technologies for the programme

Term	Definition	Source
A medical device	'any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and 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 [disability], • 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'	European Parliament and the Council of the European Union (2007) Council Directive 2007/47/EC of 5 September 2007 amending Council Directive 93/42/EEC concerning medical devices

Term	Definition	Source
An active medical device	'any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity'	Council of the European Communities (1990) Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)
An active implantable medical device	'any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure'	Council of the European Communities (1990) Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)
An in vitro diagnostic medical device	'any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: • concerning a physiological or pathological state, or • concerning a congenital abnormality, or • to determine the safety and compatibility with potential recipients, or • to monitor therapeutic measures.	European Parliament and the Council of the European Union (1998) Council Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices

A **diagnostic technology** is a medical technology with a diagnostic purpose. Diagnostic technologies are a subset of medical technologies.

Genetic tests are covered by the Programme provided they have a medical purpose and fall within the scope of Council Directive 98/79/EC.