# Chapter 2: Classification

## Section 5 - Classification of general medical devices

### Background

5.1 Under regulation 7 of the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations), general medical devices are classified into four classes of increasing levels of risk: **Class I, IIa, IIb or III** in accordance with criteria in the UK medical devices regulations, Annex IX (as modified by Schedule 2A to the UK medical devices regulations). These criteria are often called "classification rules". Examples of classification are given below:

a. Class I – lowest risk e.g. syringes without needles, medicine spoons, spectacle frames, standard adhesive bandages, examination lights
b. Class IIa – e.g. short-term corrective contact lenses, suture needles, standard hearing aids, TENS devices
c. Class IIb – e.g. apnoea monitors, ventilators, surgical lasers, diagnostic X-ray sources
d. Class III – highest risk e.g. pacemakers, total hip joint replacement system, breast implants, contraceptive IUDs, devices containing medicinal substances

5.2 Manufacturers need to demonstrate that their medical device meets the relevant requirements in the UK medical devices regulations by carrying out an assessment, known as a conformity assessment. The assessment required, and whether / the extent to which it involves an Approved Body, depends on the device's classification.

5.3 For example, a low risk medical device, such as a plaster, would fall into Class I and would not need to be assessed by an Approved Body. A higher risk medical device would need to be assessed by an Approved Body, but the depth and nature of the assessment would depend on the risk class of the medical device. For example, a tracheostomy tube would need to be assessed less rigorously then a heart valve.

5.4 If a dispute arises between a manufacturer and an Approved Body over the classification of a medical device, the MHRA can determine the classification of the device (under regulations 7(2) or 52(2) of the UK medical devices regulations).

5.5 Since the classification rules were established for medical devices, there has been significant technological progress. We consider that the existing classification rules are, in some respects, out of step with best international practice - particularly for implantable medical devices such as surgical mesh and software as a medical device.

5.6 We now have the opportunity to amend the classification rules to reflect changes in technology and better account for how medical devices are used - including the level of invasiveness and potential toxicity of certain devices. We are considering whether the classification rules within the UK medical devices regulations could be updated to

better align with best international practice and ensure that the scrutiny a medical device receives is commensurate with the level of risk that the device presents.

5.7 Further discussion and questions on medical device classification can be found in the following sections of this consultation:

a. classification of software as a medical device is covered in Chapter 10,
b. taking into account environmental sustainability and public health impacts in Chapter 13
c. classification of IVDs is covered in Chapter 9.

## Possible Changes and Questions

5.8 The MHRA considers that the classification rules for general medical devices (excluding IVDs) in the UK medical devices regulations could be amended to change the classification of certain devices, and bring into scope of the classification rules, products that did not previously fall within the definition of a medical device or within the scope of the classification rules. Examples of changes that could be made include those set out in paragraph 5.9.

5.9 The classification rules could be amended to provide as follows:

- **active implantable medical devices** and their accessories could be classified as Class III
- **in vitro fertilisation (IVF)** and assisted reproduction technologies (ART) could be classified as Class III
- **surgical meshes** could be classified as Class III
- **total or partial joint replacements** (except ancillary components such as screws, wedges, plates and instruments) could be classified as Class III
- **spinal disc replacement implants and implantable medical devices that contact the spinal column** (except ancillary components such as screws, wedges, plates and instruments) could be classified as Class III
- **medical devices incorporating nanomaterial** could be classified between Class IIa – III depending on potential internal exposure levels
- **non-invasive medical devices which come into contact with mucous membrane** (not only injured skin) could be classified between Class I – IIa depending on intended use. Injured skin or mucous membrane could mean an area of skin or a mucous membrane presenting a pathological change or change following disease or a wound
- **invasive medical devices with respect to body orifices, other than surgically invasive medical devices, which are intended to administer medicinal products** by inhalation could be classified as Class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life-threatening conditions, in which case they could be classified as Class IIb
- **medical devices that are composed of substances or of combinations 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 could be classified as:

    - class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;
    - class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body
    - class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and
    - class IIb in all other cases.
- **active therapeutic medical devices with an integrated or incorporated diagnostic function** which significantly determines the patient management by the medical device, such as closed loop systems or automated external defibrillators, could be classified as class III.

5.10 We anticipate that such changes would require substantial amendments to existing classification rules, classification definitions and implementing rules.

**Q5.1 Do you think the classification rules for general medical devices in the UK medical devices regulations should be amended in any or all of the ways set out in paragraphs 5.8-5.10? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q5.2 If you have answered 'yes' to question 5.1, please specify which of the amendments should be made.**

**Q5.3 Please outline any other amendments which should be made to the classification rules (including implementing rules and related definitions).**

**Q5.4 Please provide your reasoning (including any relevant evidence) to support your answer to questions 5.1-5.2, including any impacts on you or other stakeholder groups.**