# APPENDIX VII - CLASSIFICATION RULES FOR SURGICAL INSTRUMENTS AND APPLIANCES

**What Classification rules apply?**

The actual classification will depends on the claims made by the manufacturer and on its intended use. While the provision of illustrative examples in the table that follows is helpful when interpreting the purpose of each rule, it must be emphasised that the actual classification of a particular surgical instrument and appliance must be considered individually, taking account of its design and intended use.

Classification rules are based on different criteria such as the duration of contact with the patient, the degree of invasiveness and the part of the body affected by the use of the surgical instrument and appliance.

In these guidelines the category of the invasive surgical instruments and appliances will be considered using rules based system and the rules applied will be **5, 6, 7, and 8** as out lined in the table below:

1. Invasive appliance / instrument intended to be used to penetrate body orifices.
2. Surgically invasive appliance / instrument intended for transient use.(less than 60 minutes)
3. Surgically invasive appliance / instruments intended for short-term use.(between 60 minutes to 30 days)
4. Surgically invasive appliance / instruments for long-term use and implantable devices.(more than 30 days)

**RULE 5: INVASIVE APPLIANCES/INSTRUMENTS INTENDED TO BE USED TO PENETRATE BODY ORIFICES**

This rule covers appliance/instruments that enter the body through existing body orifices (for example, ear, mouth, nose, eye) and surgically created stomas. Appliances / instruments covered by this rule tend to be for diagnostic and therapeutic use in particular specialties (ear, nose, and throat; ophthalmology; dentistry; proctology; urology; and gynaecology).

| **Rule 5** | **Description** |
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| 5(a) Invasive appliance/instruments that are not connected to an active medical appliance, or are intended for connection to a Class A medical appliance only and are for transient use—Class A.  | Examples: handheld dental mirrors, dental impression materials, exam gloves, prostatic balloon dilation catheters.  |
| 5(b) Invasive appliance/instruments that are not connected to an active medical appliance, or are intended for connection to a Class A medical appliance/instrument only and are for short-term use—Class B.  | Examples: hard contact lenses, urinary catheters, tracheal tubes, stents, perineal reduction devices.  |
| 5(c) Invasive appliance/instrument that are for short-term use in the oral cavity as far as the pharynx, in an ear canal to the ear drum, or in a nasal cavity—Class A.  | Examples: dressing for nose bleeds, dentures removable by the patient.  |
| 5(d) Invasive appliance/instrument that are not connected to an active medical appliance/instrument, or are intended for connection to a Class A medical appliance only and are for long-term use—Class C.  | Examples: long-term urinary catheters, artificial eyes, urethral stents, contact lenses for long-term continuous use.  |
| 5(e) Invasive appliance/instrument for long-term use in the oral cavity as far as the pharynx or in an ear canal to the ear drum, or in a nasal cavity and are not liable to be absorbed by the mucous membrane—Class B.  | Examples: orthodontic wire, fixed dental prostheses, fissures sealants.  |
| 5(f) Invasive appliance/instrument with respect to body orifices, to be connected to an active medical appliance that is classified as Class B or higher—Class B.  | Examples: tracheostomy tubes connected to a ventilator, powered nasal irrigators, nasopharyngeal airways, heat and moisture exchangers, suction catheters or tubes for stomach drainage. (Independent of the time for which they are invasive)  |

**RULE 6: SURGICALLY INVASIVE APPLIANCES/INSTRUMENTS INTENDED FOR TRANSIENT USE**

This rule covers appliance/instrument that are to be used continuously for less than 60 minutes and are used to create

a conduit through the skin (needles, cannulae), surgical instruments (scalpels, saws) and various types of

catheters, suckers

| **Rule 6** | **Description** |
| --- | --- |
| 6(a) Surgically invasive appliance/instrument for transient use—Class B.  | Examples: suture needles, hypodermic needles and syringes, suckers, surgical swabs, surgical gloves.  |
| 6(b) A reusable surgical appliance/instrument —Class A.  | Examples: scissors, artery forceps, tissue forceps, tissue clamps, excavators, osteotomes, chisels.  |
| 6(c) A surgically invasive appliance/instrument for transient use to supply energy in form of ionising radiation—Class C.  | Examples: catheters containing or incorporating radioactive isotopes where the isotope is not intended to be released into the body.  |
| 6(d) A surgically invasive appliance/instrument for transient use to have a biological effect or be wholly or mainly absorbed—Class C.  | Where the biological effect is an intended one rather than unintentional. e.g. bone wax “Absorption” refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body This rule does not apply for substances that are excreted without modification from the body *i.e.* insufflation gases for the abdominal cavity  |
| 6(e) A surgically invasive appliance/instrument for transient use to administer medicine via a delivery system, and where the administration is potentially hazardous to the patient—Class C. | Devices for repeated self-application where the dose and the medicine are critical. Examples: personal insulin injectors (commonly referred to as ‘pens’). |
| 6(f) Surgically invasive appliance/instrument intended for use in direct contact with the central nervous system – Class D |   |
| 6(g) Surgically invasive appliance/instrument for transient use to diagnose, monitor, control or correct a defect of the heart, or central circulatory system through direct contact—Class D.  | Examples: cardiovascular catheters, angioplasty balloon catheters, coronary artery probes.  |

**RULE 7: SURGICALLY INVASIVE APPLIANCES/INSTRUMENTS INTENDED FOR SHORT-TERM USE**

This rule covers appliance/instrument to be used continuously for at least 60 minutes but not more than 30 days and are used in the context of surgery or post-operative care (for example, clamps and drains), infusion devices (cannulae and needles) and catheters of various types.

| **Rule 7** | **Description** |
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| 7(a) Surgically invasive appliance/instrument for short-term use—Class B.  | Examples: clamps, infusion cannulae, skin closure devices or temporary filling materials, some surgical retractors for example, chest retractors for cardiac surgery.  |
| 7(b) A surgically invasive appliance/instrument for short-term use to administer medicine - Class C.  | Examples: intravenous cannulae.  |
| 7(c) A surgically invasive appliance/instrument for short-term use to undergo a chemical change in a patient’s body (except a appliance/instrument intended to be placed in the teeth) - Class C.  | Examples: surgical / tissue adhesives.  |
| 7(d) A surgically invasive appliance/instrument for short-term use to supply energy in the form of ionising radiation - Class C.  | Examples: bradytherapy devices.  |
| 7(e) A surgically invasive appliance/instrument for short-term use to have biological effect—Class D.  | Examples: haemostatic sponge.  |
| 7(f) A surgically invasive appliance/instrument for short-term use to be wholly, or mostly, absorbed by a patient’s body—Class D.  | Examples: absorbable sutures.  |
| 7(g) A surgically invasive appliance/instrument for short-term use to be used in direct contact with the central nervous system—Class D.  | Examples: neurological catheters, cortical electrodes, connonoid paddles.  |
| 7(h) A surgically invasive appliance/instrument for short-term use to be specifically used to diagnose, monitor, control or correct a defect of the heart, or central circulatory system, through direct contact with these parts of the body—Class D.  | Examples: cardiovascular catheters, cardiac output probes and temporary pacemaker leads, thoracic catheters intended to drain the heart, including the pericardium and a carotid artery shunt.  |
| 7(i) A surgically invasive appliance for short-term use that is intended by the manufacturer to be placed in the teeth and to undergo a chemical change in the body—Class B. *Note: for this clause, a medical* appliance/instrument *to be placed in the teeth includes an* appliance/instrument *that is intended to penetrate a tooth but that does not enter the gum or bone beyond the tooth.*  | Examples: dental adhesives used for root canal therapy.  |

**RULE 8: SURGICALLY INVASIVE APPLIANCES/INSTRUMENTS FOR LONG-TERM USE AND IMPLANTABLE APPLIANCES/INSTRUMENTS**

Appliances covered by this rule include implants used in orthopedic, dental, ophthalmic and cardiovascular fields.

In addition, soft tissue implants used in plastic surgery are covered by this rule.

| **Rule 8** | **Description** |
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| 8(a) All implantable appliances/instruments and surgically invasive appliances/instruments for long-term use and implantable appliances—Class C.  | Examples: implantable joint replacements, shunts, stents, nails, plates and screws, intra-ocular lenses, infusion ports, peripheral vascular grafts, bone cements, maxillo-facial implants.  |
| 8(b) A surgically invasive appliance/instrument for long-term use to be placed in the teeth—Class B.  | Examples: bridges and crowns.  |
| 8(c) A surgically invasive appliance/instrument for long-term use to be used in direct contact with the heart, the central circulatory system or the central nervous system—Class D.  | Examples: prosthetic heart valves, aneurysm clips, vascular prostheses, spinal stents, vascular stents, CNS electrodes, cardiovascular sutures.  |
| 8(d) A surgically invasive appliance/instrument intended to be life supporting or life sustaining—Class D  | Example: pacemakers  |
| 8(e) A surgically invasive appliance/instrument intended to be active implantable medical device—Class D  |
| 8(f) An *implantable* accessory to an active implantable medical appliance/instrument—Class D.  | Example: electrode leads associated with pacemakers, defibrillators, nerve stimulators.  |
| 8(g) An active appliance/instrument to control, monitor or directly influence the performance of an active implantable medical appliance/instrument—Class D.  | Example: clinician’s programming device for pacemakers, patient control device for nerve stimulation devices.  |
| 8(h) A surgically invasive appliance/instrument for long-term use intended by the manufacturer to have a biological effect—Class D.  | Implants claimed to be bioactive (Hydroxyapatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer)  |
| 8(i) A surgically invasive appliance/instrument for long-term use to be wholly, or mostly, absorbed by a patient’s body—Class D.  | Examples: absorbable sutures, bioactive adhesives and implants through the attachment of surface coatings such as phosphorylcholine.  |
| 8(j) A surgically invasive appliance/instrument for long-term use to administer medicine—Class D.  | Examples: rechargeable non-active drug delivery systems.  |
| 8(k) A surgically invasive appliance/instrument for long-term use to undergo a chemical change in the patient’s body (except an appliance/instrument that is to be placed in the teeth)—Class D.  | Examples: surgical adhesive.  |
| 8(l) Breast Implants – Class D  |
| 8(m) A surgically invasive appliance/instrument for long-term use that is intended by the manufacturer to be placed in the teeth and to undergo a chemical change in the body is Class B. *Note: for this rule a medical device to be placed in the teeth includes a device that is intended to penetrate a tooth but does not enter the gum or bone beyond the tooth.*  | Examples: dentine adhesives.  |