



**COMPETENT AUTHORITY (UK)**  
**BULLETIN No. 10**  
**THE CLASSIFICATION RULES**  
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## **INTRODUCTION**

This information bulletin is the tenth in a series and sets out to explain in broad terms the rules in Annex IX of the Medical Devices Directive (93/42/EEC, published in the Official Journal on 12 July 1993 (L169) concerning the Classification of devices covered by that Directive and how they are designed to work. It is not intended to be a complete and definitive statement.

## **BACKGROUND**

The Directive covers a vast range of products from first-aid bandages and walking frames to CT scanners and non-active implants. While the use of many of these presents no danger, others may carry significant risks to patients or users. However, to apply the strictest controls to all products would require some manufacturers to set up additional, costly, and unnecessary procedures. It is important, therefore, that the level of control is matched, as far as possible, to the degree of risk inherent in the device. Attempts were therefore made to set the controls relative to the perceived risk in an effort to make them as relaxed as possible (thus easing the bureaucratic and financial burdens on business) and as strict as necessary (thus ensuring that the health of the patient and user is adequately protected)

## **THE CLASSES**

Devices covered by the Directive are grouped into 4 classes as follows –

**Class I** - generally regarded as low risk

**Class IIa** - generally regarded as medium risk

**Class IIb** - generally regarded as medium risk

**Class III** - generally regarded as high risk

The difference between each Class rests in the choice of conformity assessment procedures available - (See Bulletin No 4).

## **THE LAYOUT OF ANNEX**

The Annex opens with a series of Definitions (invasive, active, IX long-term etc) so as to minimise any possible ambiguities. There follows a series of implementing Rules which lay down the basic principles, such as "If more than one rule applies to a device, the highest classification stands".

## THE AIMS OF THE RULES

The Rules are a set of broad statements relating to situations, functions, parts of the body treated, properties etc, rather than a list of products which would require constant updating. This has the merit of being more flexible and better able to accommodate new developments in medical technology.

There are 4 groups within the Rules as follows –

Rules 1-4 - non-invasive devices

Rules 5-8 - invasive devices

Rules 9-12 - additional Rules applicable to active devices

Rules 13-18 - miscellaneous Rules for products which merit a higher classification than they might otherwise be assigned

## THE RULES

**RULE 1** places any non-invasive product in Class I if other Rules do not apply.

**RULE 2** places products which channel and store blood and other body liquids for administration into the body in Class IIa, except blood bags which will be Class IIb (see Rule 18). Products for storing and channelling other substances will be in Class I unless they are connected to an active medical device in a higher Class, in which case they are in Class IIa.

**RULE 3** places products which alter the biological or chemical composition of blood or other liquids introduced into the body in Class IIb unless the treatment consists of filtration, centrifugation or exchange of gas or heat, in which case they are in Class IIa.

**RULE 4** covers non-invasive devices, which come into contact with injured skin. This Rule covers dressings and can place them in Class I in the simplest cases (sticking plaster) or Class IIa. More complex products, such as those which are intended principally for use with wounds which have breached the dermis and can only heal by secondary intent, are in Class IIb.

**RULE 5** covers only devices which are invasive with regard to body orifices ie it does not cover surgically invasive devices. The devices covered can be in Class I, Class IIa or Class IIb depending on the duration of continuous use and the degree to which they are inserted in the body. If they are intended for connection to an active device they are regarded as Class IIa products.

**RULES 6, 7 AND 8** all cover surgically invasive devices and are applicable depending on the duration of continuous use. They are more complex than earlier Rules because they contain exceptions relating to specific functions (such as being specially designed for use where there are defects in the central circulatory system or the heart) or specific properties (such as emitting ionising radiation or being absorbable). Basically, products will be in Class IIa if they are for transient or shortterm use and in Class IIb for long-term use. But they will move up into a higher class if they additionally have special properties such as those mentioned above.



One exception is that simple reusable surgical instruments are in Class I

**RULE 9** covers active therapeutic devices, which administer or exchange energy. They will generally be in Class IIa, but in particular cases may be in Class IIb if they carry out their function in a potentially hazardous way.

**RULE 10** covers active diagnostic devices. They are in Class IIa if they supply energy (other than for illumination) absorbed by the body or if they monitor physiological processes or if they image in vivo distribution of radiopharmaceuticals. They may be in Class IIb if they are used for similar monitoring but intended specifically for critical situations. Radiological equipment will also generally be in Class IIb.

**RULE 11** covers all active devices (whether therapeutic or diagnostic in purpose) which administer or remove substances (including medicines and body liquids). These will be in Class IIa but may be in Class IIb if they carry out their function in a potentially hazardous way.

**RULE 12** covers all other active devices and places them in Class I.

**RULE 13** assigns the highest classification (Class III) to devices which incorporate a substance which would be considered as a medicinal product if placed on the market separately and that substance liable to assist or enhance the functioning of the device itself. Examples are heparin-coated catheters and bone-cement containing an antibiotic.

**RULE 14** places condoms and other contraceptive devices in Class IIb. All intra-uterine contraceptive devices, however, will be in Class III.

**RULE 15** covers cleaning and disinfecting products specifically designed for use with medical devices. They will be in Class IIa, except for contact lens care products which will be in Class IIb.

**RULE 16** covers x-ray film which will be in Class IIa.

**RULE 17** covers devices incorporating animal tissues which have been rendered non-viable and places them in Class III, except where such devices are intended to come into contact with intact skin only when they will be governed by other rules.

**RULE 18** covers blood bags and places them in Class IIb.

## **HOW THE PROCESS WILL WORK**

It is initially for the manufacturer to determine the classification of his product(s). This will allow him to select a Notified Body, if required, with the ability to carry out the appropriate conformity assessment procedure. It will then be for that Notified

Body to confirm the classification arrived at by the manufacturer before embarking upon the process of conformity assessment. In the event that the manufacturer and the Notified Body cannot agree on the classification either party can refer the matter for a decision to the Competent Authority which designated the Notified Body. If doubt still exists the EC Commission, acting in conjunction with a Regulatory Committee composed of experts from the Member States may be approached for a ruling. Similarly, the EC Commission, in conjunction with the Regulatory Committee, may adapt the Rules if experience shows this to be necessary.

## **FURTHER INFORMATION**

Further information about Classification and the Directive, and copies of other Bulletins in the series, can be obtained from our website <http://www.mhra.gov.uk> or For more detailed enquiries ring **T** 020 3080 7300 or E-mail: [era@mhra.gsi.gov.uk](mailto:era@mhra.gsi.gov.uk) or write to:

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