Commission communication on the application of transitional provision of Directive 93/42/EEC relating to medical devices
(98/C 242/05)

This communication refers to Article 22(4) of Directive 93/42/EEC concerning medical devices. It aims at providing clarification on the aforementioned provision in order to ensure its uniform application throughout the European Community.

Article 22(4) of Directive 93/42/EEC requires Member States to continue to accept the placing on the market and the putting into service of devices which conform to the rules in force in their territory on 31 December 1994 pre-existing national rules) for a period of five years following the adoption of the aforementioned Directive, i.e. ending on 14 June 1998.

Accordingly, since 1 January 1995, when Directive 93/42/EEC became first applicable, it has been possible to place medical devices on the market and put them into service either in accordance with the pre-existing national rules or in compliance with Directive 93/42/EEC. From 15 June 1998, it will only be possible to place medical devices on the market and put them into service if they comply with Directive 93/42/EEC.

The term 'placing on the market' is defined in Article 1(2)(h) of Directive 93/42/EEC as the 'first making available in return for payment or free of charge of a device ... with a view to distribution and/or use on the Community market regardless of whether it is new or fully refurbished'. 'Putting into service' means in accordance with Article 1(2)(i), 'the stage at which a device is ready for use on the Community market for the first time for its intended use'. The concepts of placing on the market and putting into service refer to each individual product, and not to a type of device.

The provision of Article 22(4) applies in relation to devices placed on the market prior to 15 June 1998 in compliance with the pre- existing national rules of Member States. Member States may require evidence on compliance with such rules and, where no specific rules exist, on the assurance of an adequate level of safety of devices based on general safety considerations.

Regarding the 'putting into service' of those devices, the Commission considers that a device reaches this stage as soon as it is ready for use in the Community.

To a large extent, devices covered by Directive 93/42/EEC are ready for use at the time they are placed on the market by the manufacturer. In fact, distribution or other manipulations make no difference to their safety and performance, provided manufacturers' instructions have been followed. These devices are considered as being put into set-vice at the same time as they are placed on the market. Therefore, such devices which have been made available by the manufacturer up to and including 14 June 1998 may, after that date, continue to be transferred to end-users and used in accordance with pre-existing national rules.

Some devices, prior to their use, need further processing, for instance sterilisation of surgical dressings, preparation of dental filling material, soaking and fitting of contact lenses. Such kind of processing by the end-user, according to its needs, is assigned to products by the manufacturer as part of the intended use. Relevant devices should be considered as being ready for use, even if the aforementioned processing by the end-user has not yet taken place.

However, devices placed on the market which, in view of their first use, need to be assembled or installed in the hospital and where these manipulations have an impact on safety and/or performances of the devices, are not considered as 'put into service', unless the aforementioned activities have been carried out.

It should be noted that Article 22(4) as well as the definition of 'putting into service' within the meaning of Directive 93/42/EEC are currently under revision (*'*). Once the forthcoming amendment of Article 22(4) which is currently going through the legislative procedure will become applicable, the present interpretation will cease to apply.

See Article 21(2)(g) of the common position adopted by the Council on 23 March 1998 with a view to adopting Directive 98/ ... /EC of the European Parliament and the Council on in-vitro diagnostic medical devices.