INTERPRETATIVE DOCUMENT

of the Commission's Services

INTERPRETATION OF THE RELATION BETWEEN THE REVISED DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES AND DIRECTIVE 89/686/EEC ON PERSONAL PROTECTIVE EQUIPMENT

Background

(1) Some products can be qualified as personal protective equipment as well as medical devices. These products are thus intended for 'dual use'. For example, gloves with a medical purpose in the patient environment are medical devices, but as they are also designed to provide protection to the user, they also fall into the definition of personal protective equipment..

(2) According to the original Article 1(6) of the MD Directive, prior to amendment by Directive 2007/47/EC, the MD Directive did not apply to personal protective equipment covered by Directive 89/686/EEC.

(3) The legal situation was that double "CE" marking was not allowed with the following consequences:

- manufacturers may use the basic health and safety requirements of the PPE Directive to ensure that the intended user is protected, or

- manufacturers may use the essential requirements of the MD Directive to ensure that the medical device is safe and performing as intended.

Revised Article 1 (6) MD Directive

(4) In the light of the discussions during the negotiations of the proposed revision, it became apparent that, where the manufacturer wants to market a product as a medical device and also as a personal protective equipment, the essential requirements of both Directives need to be applicable.

(5) The amendment to Article 1 (6) MD Directive now reads:

"Where a device is intended by the manufacturer to be used in accordance with both the provisions on personal protective equipment in Council Directive 89/686/EEC and this Directive, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled." (Article 2 (l)f of Directive 2007/47/EC).

(6) The consequence of this amendment is that dual use products (MD and PPE) are covered by the MD Directive.

(7) This amendment allows manufacturers to submit their medical device, intended for 'dual use' to a conformity assessment procedure under the MD Directive, which, as the product is also PPE, must include the relevant basic health and safety requirements of the PPE Directive.

(8) The amendment specifically uses the term 'relevant', as some requirements of the PPE Directive are not applicable or already covered by the essential requirements of the MD Directive.

(9) The medical device must be affixed with CE marking under the MD Directive.

(10) In this way, manufacturers who desire to sell products with 'dual use' may now use, under the MD Directive, one single evaluation of the conformity procedure allowing an assessment of all risks set out in both regimes.