

# SBA POSITION PAPER

## CE Marking of Primary Packaging for Terminally Sterilised Medical Devices

The SBA supports the opinion expressed by Maurice Freeman at the meeting of CEN/TC102/WG4 which was held in Berlin on 6 and 7<sup>th</sup> May 1997.

Mr Freeman, a consultant to the European Commission on CEN matters, stated that he believed the position of the Commission to be:

- Packaging material is considered to be part of a medical device when it is used to maintain the sterility of the device placed on the market in a sterile condition. As such it does not require its own CE mark. The CE mark which appears on the packaging material will relate to the medical device and not to the packaging itself.
- Packaging material intended to be used to maintain the sterility of a medical device after sterilisation, which is sold separately from the device (e.g. to hospitals to wrap medical devices for in-house sterilization), is considered to be an accessory to a device. As such it requires a CE mark. This mark can be placed
  - either on the packaging material itself,
  - or on the sales packaging associated with it (e.g. the label on the outside of a reel of packaging material or a box of pouches)

To avoid confusion, it will usually be preferable to place the CE mark on the sales packaging rather than on individual pouches, bags, sheets, etc