

Ms Genny Crockett
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Your Ref :
Our Ref : E/98/0834

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2 March 1998

Dear Ms Crockett,

CE MARKING : ADAPTED SCISSORS AND GARDEN HAND TOOLS

Thank you for your letter of 6 February 1998.

The MDA is willing to, and does give general guidance on questions arising under the Regulations on medical devices. However, it is not part of its functions under the Directive or the Regulations to give decisions as to whether a particular product is or is not a medical device. These are questions for manufacturers to decide. They should not rely on the views of the MDA but should make decisions in conjunction with advice from their own lawyers or other professional advisors. Any opinion or guidance given by the MDA as to whether a product is or is not a medical device is not intended to and can have no legal consequences and an authoritative ruling can be given only by a court. What we say below must be read in the light of these comments.

In our opinion technical aids intended for leisure and recreation as well as the simpler devices that assist feeding, dressing and housekeeping should not usually be eligible for CE Marking. We would consider that the above items would fall into this category and are not therefore eligible for CE Marking.

If we can be of further assistance in this matter please do not hesitate to contact us again.

Yours sincerely,


Higgins R A Mr