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The definition of a medical device as identified in the Medical Device Directive 93/42/EEC, Article 1, Definitions, Scope is as follows:

(a) 'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

(b) 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

As you can see, a blade remover does not fall within either of these categories. The intended use of a blade remover is to assist the user in safely removing a used blade from a handle.
A letter has been obtained from the UK Competent Authority that identifies "Products that are intended for the safe disposal of medical devices are not deemed to have a medical purpose".

I hope that this clarifies the situation in identifying that a blade remover is not classed as a medical device and therefore there are no requirements to CE mark the product.

Darren Hall
QA/RA Systems Manager