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RESPONSIBILITIES IN THE USE OF WOUND CARE PRODUCTS

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The quasi totality of the wound care products fall within the scope of Directive 93/42/EEC. The directive aims at harmonizing the requirements for the placing on the market and putting into service of medical devices through the EU. It assigns a set of responsibilities to the Competent Authorities and to the manufacturer, who has to clearly specify under which conditions its product scores a positive benefit/risk ratio for the patient. Such conditions may also include: typology of the wound to be treated, length of the treatment, counter-indication, mode of application and shelf life.

Any use outside such conditions has not been verified and, consequently, the benefit/risk ratio has not been determined. Whoever uses a medical device outside the specifications given by the manufacturer, does it under his/her full responsibility and could be considered liable for any adverse event linked to such use.

Users shall therefore carefully evaluate the conditions under which the devices can be used and purchase and use them in accordance to the specifications.

It is therefore paramount that the medical profession clearly spells out to the manufacturers the needs they have for the treatments for which they are responsible.